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AIDS TREATMENT AND CARE: WHO CARES?

FOURTEENTH REPORT

BY THE

COMMITTEE ON GOVERNMENT OPERATIONS

together with
DISSENTING VIEWS



AUGUST 14, 1990.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

U.S. GOVERNMENT PRINTING OFFICE

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LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
Washington, DC, August 14, 1990.

Hon. THOMAS S. FOLEY,
Speaker of the House of Representatives,
Washington, DC.

DEAR MR. SPEAKER: By direction of the Committee on Government Operations, I submit herewith the committee's fourteenth report to the 101st Congress. The committee's report is based on a study made by its Human Resources and Intergovernmental Relations Subcommittee.

JOHN CONYERS, Jr., *Chairman.*

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AIDS TREATMENT AND CARE: WHO CARES?

AUGUST 14, 1990.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. CONYERS, from the Committee on Government Operations,
submitted the following

FOURTEENTH REPORT

together with

DISSENTING VIEWS

BASED ON A STUDY BY THE HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE

On August 2, 1990, the Committee on Government Operations approved and adopted a report entitled "AIDS Treatment and Care: Who Cares?" The chairman was directed to transmit a copy to the Speaker of the House.

I. INTRODUCTION AND BACKGROUND

Under the rules of the House of Representatives, the Committee on Government Operations has responsibility for studying, on a continuing basis, the operation of Government activities at all levels. The Committee has assigned this responsibility, as it pertains to the Department of Health and Human Services (HHS), to the Human Resources and Intergovernmental Relations Subcommittee.

Pursuant to its authority, the subcommittee conducted a review of HHS' role in the outpatient treatment and care of persons who are infected with the human immunodeficiency virus (HIV), with a focus on ambulatory care. This includes persons at any point along the spectrum of HIV disease—those with acquired immune deficiency syndrome (AIDS) or AIDS-related complex (ARC), as well as those who are infected but asymptomatic.

The subcommittee held oversight hearings on July 28 and August 1, 1989.¹ On July 28, the witnesses were Mr. John Overrocker, accompanied by Bill Ceyrolles, a social worker; Peter S. Arno, Ph.D., Health Economist, Department of Epidemiology and Social Medicine, Montefiore Medical Center, Albert Einstein College of Medicine; Lawrence S. Brown, Jr., M.D., M.P.H., Senior Vice President for Research and Medical Affairs, Urban Resource Institute, Addiction Research and Treatment Corporation; Paul S. Jellinek, Ph.D., Senior Program Officer, The Robert Wood Johnson Foundation; Wafaa El-Sadr, M.D., Chief, Infectious Disease Section, Harlem Hospital Center; David Smith, M.D., Medical Director, Community Oriented Primary Care, Parkland Memorial Hospital; Donald E. Craven, M.D., Director, Clinical AIDS Programs, Boston City Hospital; Mr. Cornell Scott, Executive Director, Hill Health Center; Nicholas Rango, M.D., Director, AIDS Institute, New York State Department of Health; Ms. Pat Christen, Acting Executive Director, San Francisco AIDS Foundation; and Ms. Jean F. McGuire, Executive Director, AIDS Action Council.

On August 1, the subcommittee heard from a physician and witnesses representing the Federal Government. They were Paul A. Volberding, M.D., Associate Professor of Medicine, University of California at San Francisco, and Chief, AIDS Program, San Francisco General Hospital; and Honorable James O. Mason, M.D., Assistant Secretary for Health, Department of Health and Human Services, accompanied by Samuel C. Matheny, M.D., M.P.H., Associate Administrator for AIDS, Health Resources and Services Administration; Edward D. Martin, M.D., Director, Bureau of Health Care Delivery and Assistance, Health Resources and Services Administration; Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health; Frank Young, M.D., Commissioner, Food and Drug Administration; Ellen C. Cooper, M.D., Director, Division of Antiviral Drug Products, Office of Drug Evaluation, Center for Drug Evaluation and Research, Food and Drug Administration; and Mr. Elmer Smith, Director, Office of Eligibility Policy, Bureau of Policy Development, Health Care Financing Administration.

The HIV epidemic has brought into sharp focus the deplorable state of health care in the U.S. Many urban hospital systems are reeling under the weight of AIDS, drug addiction, homelessness and mental illness. Access to adequate care is unavailable to many Americans. As many as 37 million are uninsured. Medicaid offers varying degrees of assistance to poor persons from State to State, and those whom it covers frequently have difficulty finding care providers willing to accept the low reimbursement rates offered in many States.

Kristine Gebbie, a member of the Presidential Commission on AIDS, expressed the commission's concerns about health care in America this way: "We looked at the American system through the lens of the HIV-infected and found gaping holes, huge problems.

¹ Hearings before a subcommittee of the Committee on Government Operations, U.S. House of Representatives, "Treatment and Care for Persons With HIV Infection and AIDS," June 28 and August 1, 1989, hereafter referred to as Hearing.

We said that if the country does not do something about all these problems, we will never stop the epidemic.”² We agree.

The following developments related to the AIDS epidemic provide reasons why we must have a national plan to combat the HIV epidemic:

The U.S. Centers for Disease Control (CDC) estimates that there is an overwhelming number of infected persons in the U.S.—between 1,000,000 and 1,500,000.

CDC has recommended treatment for asymptomatic HIV-infected persons to delay the onset of serious illness.

The health care systems of the most AIDS-impacted communities of this country are overburdened with the results of HIV infection, drug abuse, homelessness and poverty.

The AIDS epidemic first targeted gay and bisexual men, and now is spreading more rapidly among the most vulnerable segments of U.S. society—drug users, ethnic and racial minorities, women, adolescents, and the poor among us.

The States and cities with the highest incidence of HIV disease are unable to finance the various kinds of care needed by all their residents with HIV disease.³

As Robert Hummel, Assistant Commissioner for Health in New Jersey said, “We, as a nation, are totally unprepared to deal with the impact of these recent developments, and until we make HIV care and treatment a national priority, HIV will continue to kill off our population as effectively as any war past, present or future.”⁴

The civil servants in the Public Health Service have, from the beginning of the epidemic, attempted to measure its extent and direction, create and conduct prevention programs, generate new treatments, and provide health care assistance to communities in need. They have achieved much, but their efforts have been limited by the absence of leadership at the highest levels of our Federal Government and the lack of a national plan for addressing the epidemic.

A. EPIDEMIOLOGY AND PROJECTIONS

The U.S. Centers for Disease Control estimates that currently 1,000,000 persons are infected with HIV. At the end of April 1990, more than 132,500 cases and nearly 81,000 deaths had been reported to CDC. AIDS cases and deaths are expected to continue increasing during the next four years, with as many as 57,000 cases and 42,000 deaths expected in 1990 alone. By 1993, the annual count is projected to be as high as 98,000 cases and 76,000 deaths. By 1993 CDC expects that from 151,000 to 225,000 persons will be living with AIDS.⁵

² Kristine M. Gebbie, R.N., as quoted in the statement of Philip R. Lee, M.D., Institute for Health Policy Studies, University of California, San Francisco, before the National Commission on AIDS, November 3, 1989.

³ Statement of Robert F. Hummel, Assistant Commissioner, New Jersey State Department of Health, before the National Commission on AIDS, November 3, 1989.

⁴ Ibid.

⁵ “Estimates of HIV Prevalence and Projected AIDS Cases: Summary of a Workshop, October 31–November 1, 1989,” *Morbidity and Mortality Weekly Report*, February 23, 1990.

In 1987, trends in reported AIDS cases among homosexual and bisexual men, while still increasing, indicated a slower rate of increase than in previous years. Increases in diagnosed cases were greatest for intravenous drug users (IVDU's), their sexual partners, and children.⁶ The proportion of women increased from 7 percent of the cases reported in the 1986⁷ to 10 percent of those reported in 1989.⁸

Blacks and Hispanics continue to be overrepresented among reported AIDS cases in relation to their proportion of the U.S. population. Blacks account for more than 27 percent of all cases and Hispanics for nearly 16 percent. The rate per 100,000 for blacks is 77.4 and for Hispanics is 61.0 as compared with 23.3 for whites.⁹

B. HHS PROGRAMS PROVIDING TREATMENT AND CARE FOR AIDS PATIENTS

Several agencies within HHS have programs or responsibilities for AIDS treatment and care. These include the Health Resources and Services Administration and the National Institute of Allergy and Infectious Diseases in the National Institutes of Health. These two agencies are in the Public Health Service (PHS). In addition, the Health Care Financing Administration conducts the Medicaid and Medicare Programs which provide reimbursements to health care providers for services rendered. A description of the programs follows:

1. *The Health Resources and Services Administration (HRSA)*

HRSA conducts several programs that provide direct patient care services or coordination of community-based services, targeted on children and adults.

*HIV Service Demonstration Grants.*¹⁰—This program was begun in late 1986 with awards to the four cities with the highest incidence of reported AIDS cases—New York City, San Francisco, Los Angeles, and Miami. By the end of fiscal year 1989, HRSA had awarded almost \$15 million in grants to 25 metropolitan areas for the purpose of developing local coalitions of medical, social, and personal care providers within a system of case-managed, patient-oriented care for persons with HIV infection and AIDS.

HIV Planning Program for Low-Prevalence Areas.—These 1-year grants will assist cities and States less severely affected by the epidemic in planning service delivery systems to respond more effectively to the HIV epidemic. By the end of fiscal year 1990, 25 projects should be funded at a level of \$3.6 million.¹¹ However, the President's fiscal year 1991 budget did not request funds for this program.

Pediatric AIDS Demonstration Grants.—New approaches and innovative models for providing coordinated health care and support-

⁶ "Update: Acquired Immunodeficiency Syndrome—United States, 1989," *Morbidity and Mortality Weekly Report*, February 9, 1990, Volume 39, p. 81.

⁷ *AIDS Weekly Surveillance Report—United States*, Centers for Disease Control, December 29, 1986.

⁸ *HIV/AIDS Surveillance*, Centers for Disease Control, Year End Edition, January 1990.

⁹ *HIV/AIDS Surveillance*, Centers for Disease Control, February 1990.

¹⁰ Formerly called AIDS Service Demonstration Grants.

¹¹ Hearing, August 1, James O. Mason, M.D., Assistant Secretary for Health, Department of Health and Human Services, p. 255.

ive services for children and women of childbearing age, infected or at risk of infection, are the goals of these grants. Thirteen organizations were awarded grants in fiscal year 1988 at a level of \$4.4 million. In fiscal year 1989, \$7.8 million went to support a total of 17 projects and \$15 million has been appropriated for fiscal year 1990.

AIDS Drug Reimbursement Program.—This program assists low-income persons to purchase AZT and other drugs for therapeutic treatments. In fiscal year 1987, \$30 million was appropriated on an emergency basis following the approval of AZT by the FDA. In FY 1989, a total of \$20 million in additional funds were disbursed for AZT and other AIDS-related drugs with \$15 million in funds transferred from the AIDS budgets of the PHS agencies and a \$5 million gift from the Burroughs Wellcome Company (BW), manufacturers of AZT. In turn, BW was the recipient of virtually all of the \$15 million in transferred funds through the purchase of AZT. Congress has appropriated \$30 million for the AIDS drug reimbursement program for fiscal year 1990. The President's fiscal year 1991 budget requested no funds for this program.

Community Health Centers (CHC).—The 550 Community Health Centers offer direct primary health care services to medically underserved populations. Because of the overlap between areas with underserved populations and areas with a high incidence of AIDS, CHC's are especially important in the delivery of health care to persons with HIV infection and AIDS. Federal appropriations provide less than one-half of the cost of operations of the CHC's. The remainder comes from billing insurance companies, privately-raised funds and State and local contributions. For fiscal year 1990, Congress appropriated \$428 million for general primary care and an additional \$10.8 million specifically for AIDS-related care. The President's request for fiscal year 1991 was \$474 million with \$13 million for AIDS care.

2. *The National Institutes of Health (NIH)*

NIH conducts programs designed to develop and test therapeutic drugs for AIDS-related conditions. The National Institute for Allergy and Infectious Diseases (NIAID) has established a program to develop and test drugs for the treatment of AIDS-related conditions in clinical trials for children and adults. The National Cancer Institute conducts an intramural clinical testing program involving pediatric and adult patients. In addition to research, the clinical trials are viewed as an important source of treatment for persons who volunteer to participate in them.

3. *Medicaid and Medicare*

The Health Care Financing Administration (HCFA) pays for AIDS and HIV treatment and care through the Medicaid and Medicare Programs.

Medicaid is an entitlement program for poor persons who are aged, blind, disabled, or in families with children. It is funded jointly by the Federal Government and the States. The Federal Government pays, on average, 55 percent and the State pays 45 percent. The States determine, within limits established by the Federal Government, eligibility criteria and the range of covered services.

Thus, the Medicaid Program varies greatly from State to State. Eligibility among persons with AIDS is generally based on poverty and disability. Medicaid was intended to serve as the payor of last resort for persons with AIDS. The fiscal year 1990 estimate for the Federal share of Medicaid outlays for persons with AIDS is \$670 million. This amount represents 1.75 percent of the \$38.2 billion estimated for Medicaid's total Federal share.¹² Of all AIDS patients in the United States, 40 percent are served by the Medicaid Program at some point in their illness. The Medicaid Program—Federal and State—has paid about 25 percent of all AIDS-related medical care costs.

Medicare is an entitlement program entirely supported by the Federal Government. The actual expenditures under the Medicare program are largely determined by the number of eligible persons and the range of covered services. Medicare's role in financing AIDS care has been minimal, because disabled Social Security Disability Insurance recipients must wait 24 months before qualifying for Medicare benefits. For fiscal year 1990, the estimated Medicare Program expenditures for persons with AIDS ranges from \$100 million to \$150 million. These amounts represent approximately 0.1 percent of the \$108.2 billion in estimated fiscal year 1990 outlays.¹³

II. FINDINGS

A. THE PUBLIC HEALTH SERVICE HAS RECOMMENDED EARLY INTERVENTION TREATMENTS TO DELAY THE DEVELOPMENT OF AIDS IN HIV-INFECTED PERSONS BUT HAS DEVELOPED NO PLANS OR PROGRAM TO HELP PAY FOR IT

During the past year, several remarkable clinical advancements in the management of HIV infection were announced by the Public Health Service. Treatments can now delay the onset of potentially lethal diseases and conditions in persons with HIV infection and ARC.

First, the CDC recommended that persons with CD4+ cell counts below 200 per cubic millimeter be treated with a prophylaxis such as aerosol pentamidine against *Pneumocystis carinii* pneumonia (PCP), the most common presenting infection and a major cause of death among AIDS patients.¹⁴ Second, HHS announced the efficacy of AZT in delaying the progression of the disease in persons with early AIDS-related complex (ARC).¹⁵ The third breakthrough was the discovery that AZT delays the onset of symptoms in asymptomatic HIV-infected persons.¹⁶ While this application of AZT is significant in the short term, longer term benefits of this treatment strategy are unknown.¹⁷ Additional drugs are under in-

¹² The President's Fiscal Year 1991 budget request.

¹³ *Ibid.*

¹⁴ "Guidelines for Prophylaxis Against *Pneumocystis carinii* Pneumonia for Persons Infected with Human Immunodeficiency Virus," *Morbidity and Mortality Weekly Report*, June 16, 1989, Vol. 38, No. S-5, Centers for Disease Control, Department of Health and Human Services.

¹⁵ "HHS News," Department of Health and Human Services, August 3, 1989. The data from this research are awaiting publication.

¹⁶ Paul A. Volberding, Stephen W. Labakos, et al., "Zidovudine in Asymptomatic Human Immunodeficiency Virus Infection," *New England Journal of Medicine*, April 5, 1990, Vol. 322, pp. 943-949.

¹⁷ Gerald H. Friedland, "Early Treatment for HIV: The Time Has Come," *New England Journal of Medicine*, April 5, 1990, Vol. 322, p. 1000.

vestigation in clinical trials across the country that could also add to the pharmacological weapons against HIV disease in coming months and years.

AZT, as the first anti-retroviral drug to be approved for HIV treatment, has prolonged many lives. However, its toxicity has restricted its use in a substantial subset of those for whom it could otherwise be therapeutic.¹⁸ In January 1990, the Food and Drug Administration (FDA) approved a change in the labeling of AZT to half the previously recommended dose. A study conducted by NIAID's AIDS Clinical Trials Group found that the lower dose resulted in similar survival statistics, the same number of opportunistic infections, and a lower incidence of hematologic toxicity compared to the higher dose. Because toxicity is linked to the size of the dose, patients taking the lower dose are suffering fewer side effects and a smaller number will have to discontinue AZT therapy for this reason.¹⁹

These significant advances in treatment offer some hope to thousands of HIV-infected individuals. Scientists and physicians in clinical practice are asserting that AIDS is becoming a "chronic disease"—at least in some patients—one that can be managed over longer periods of time.

Of the 1,000,000 persons estimated by the Public Health Service to be currently infected with HIV,²⁰ an estimated 650,000 persons, or 65 percent of those infected, have CD4+ cell counts below 500 per cubic millimeter of blood, making those patients candidates for early treatment with AZT.²¹ As many as 200,000 persons could have CD4+ cell counts below 200 and, thus, can potentially benefit from aerosol pentamidine prophylaxis against PCP.²²

In addition to warding off opportunistic infections and prolonging life, there are other persuasive reasons for providing early intervention to infected persons. Scientists have demonstrated that in persons with HIV infection, the virus continuously replicates itself as the disease progresses.²³ It is possible that anti-viral drugs will block or reduce viral replication. If this is true, then early intervention with AZT or other anti-virals may reduce infectivity

¹⁸ Douglas D. Richman, Margaret A. Fischl, et al., "The Toxicity of Azidothymidine (AZT) in the Treatment of Patients with AIDS and AIDS-Related Complex," *New England Journal of Medicine*, Vol. 317, July 23, 1987, p. 192.

¹⁹ "FDA Drug Bulletin," Department of Health and Human Services, Vol. 21, No. 1, April 1990.

²⁰ "Estimates of HIV Prevalence and Projected AIDS Cases: Summary of a Workshop, October 31–November 1, 1989," *Morbidity and Mortality Weekly Report*, Vol. 39, February 23, 1990, p. 110.

²¹ Charles Marwick, "Expanding AIDS Drug Availability," *Journal of the American Medical Association*, September 8, 1989, Vol. 262, p. 1289; "AZT Found to Delay Onset of AIDS; Treatment Urged for Up to 650,000," Michael Specter, *Washington Post*, August 18, 1989.

²² John F. Brundage, John G. McNeil, et al., "The Current Distribution of CD4+ T-Lymphocyte Counts Among Adults in the United States with Human Immunodeficiency Virus Infections: Estimates Based on the Experience of the U.S. Army," *Journal of Acquired Immune Deficiency Syndromes*, Vol. 3, February 1990, pp. 92–94. The article states that based on the Army's experience, 17 percent of infected adults may currently have fewer than 200 CD4+ cells/mm³, which, if 1 million persons are infected, would equal 170,000 persons. The authors note that the Army's experience may underrepresent the U.S. population as a whole because (1) few Army personnel are stationed near urban epicenters of the AIDS epidemic, (2) the Army has policies that exclude overt homosexuals and IV drug users, and (3) applicants who are infected at the time of their preinduction physical are disqualified from entering the Army.

²³ David D. Ho, Tarsem Moudgil and Masud Alam, "Quantitation of Human Immunodeficiency Virus Type I in the Blood of Infected Persons," *New England Journal of Medicine*, December 14, 1989, p. 1621.

which in turn could retard transmission of the virus.²⁴ Additionally, early treatment may well result in a decrease in other infections such as tuberculosis²⁵ and syphilis²⁶ that are being seen more frequently associated with HIV.

Without early intervention, we can expect the more rapid onset of symptoms and serious illness in virtually all those who are infected. By slowing the process from infection to illness, a substantial measure of patient care can be moved from the hospital bed into the clinic, thus reducing the pressure on hospitals and reducing the cost of care, at least for awhile. And, if people are not disabled by illness, they can work and remain productive members of society for longer periods.

The Public Health Service acknowledges the necessity for treatment beyond merely administering prophylaxis to HIV-infected individuals. The "Morbidity and Mortality Weekly Report" (MMWR), published by the CDC, states:

The [early intervention] guidelines are likely to increase the demand for medical services by asymptomatic HIV-infected persons. Such persons will need medical evaluation to determine whether they are candidates for prophylaxis against PCP, and—if prophylaxis is given—these persons will need medical follow-up. All persons found to be infected at HIV counseling and testing centers should be referred for further medical evaluation, including a measurement of their CD4+ cells. Facilities offering HIV counseling and testing should develop referral networks of medical-care providers sufficient to evaluate and care for the infected persons they identify. These networks should include services related to family planning and treatment for intravenous drug addiction, sexually transmitted disease, and tuberculosis.²⁷

Dr. James O. Mason, Assistant Secretary for Health and head of the Public Health Service, was HHS' spokesperson at the subcommittee hearings. Chairman Weiss asked Dr. Mason.

. . . Would you agree that the [early intervention] services should include . . . pre- and post-test counseling for all those who are tested; monitoring of CD4 cell levels for all infected persons; primary care for those infected persons with other illnesses; monthly treatments of aerosolized pentamidine or other prophylaxis against PCP for those who have low CD4 cell counts; treatment with AZT when indicated; and continuing treatment as the disease progresses? ²⁸

²⁴ Peter S. Arno, et al., "Economic and Policy Implications of Early Intervention in HIV Disease," *Journal of the American Medical Association*, September 15, 1989, Vol. 262, pp. 1493-1498.

²⁵ Peter A. Selwyn, Diana Hartel, et al., "A Prospective Study of the Risk of Tuberculosis Among Intravenous Drug Users with Human Immunodeficiency Virus Infection," *New England Journal of Medicine*, Vol. 320, March 2, 1989, p. 545.

²⁶ T.P. Rose, W. Ford, et al., "An Association of Syphilis Episodes and Human Immunodeficiency Virus (HIV) Infection in Sexually Transmitted Disease (STD) Patients in Los Angeles County," presented at the V International Conference on AIDS, Montreal, June 1989.

²⁷ *Morbidity and Mortality Weekly Report*, June 16, 1989, p. 8.

²⁸ Hearing, August 1, Chairman Weiss, p. 263.

Dr. Mason replied:

Certainly that is an array of services that we now feel, based upon good clinical science, should be made available to individuals who are infected with HIV.²⁹

Dr. Mason again acknowledged the ramifications of early intervention for clinical services:

. . . This kind of clinical therapy requires that there be trained health care professionals. It requires laboratory services available to do the CD4 test. It requires that there be funding mechanisms to pay for these services . . . a combination of Federal, State, and local, public, private, voluntary, will find a way whereby good science-based recommendations can be implemented nationally.³⁰

Thus, the Assistant Secretary for Health and the MMWR both recommend a broad range of medical evaluation, testing, monitoring, and treatment for the patient. But, to date, no one in the Administration has addressed the basic issue of financing the delivery of these essential services.

Early intervention is not inexpensive. Health economist Peter Arno has estimated early intervention for one individual to cost \$5,094 on average. This includes clinical and laboratory monitoring during the seropositive individual's pre-treatment phase, and drug treatment including AZT, a prophylaxis against PCP and possibly other drugs in the second phase, when treatment has begun.³¹

Dr. Arno estimates the cost for the first year of a national program serving virtually all persons who are eligible for early intervention based on their CD4+ cell counts to be about \$1.2 billion.³² According to Dr. Arno, the primary basis for the high cost of early intervention is the price of drugs:

The . . . financial burden of early HIV intervention is in part artificial. The bulk of expenditures is tied to the price of pharmaceutical agents, and though drug companies have a legitimate need to recoup their investments on experimental drug development, the public also has a right to obtain lifesaving drugs at reasonable prices.³³

While early intervention costs are high, even with the recent reduction in price and dosage of AZT, viewed in the larger framework of overall Federal health care spending, they are less than one-fifth of one percent of total national health care spending, estimated at \$661 billion per year.³⁴

Access to early intervention and its life-extending results can be limited in two ways: through the absence of available services, and the lack of financial support.

²⁹ Ibid., Dr. Mason, p. 263.

³⁰ Ibid., pp. 262-263.

³¹ Peter S. Arno, testimony before the House Budget Committee Task Force on Human Resources, March 6, 1990.

³² Ibid. In his testimony at the hearing and an article in the *Journal of the American Medical Association*, Mr. Arno estimated the annual cost of early intervention to be \$5 billion. Following the reduction in the recommended dosage of AZT, he revised this estimate.

³³ Peter Arno, National Commission on AIDS Proceedings, November 3, 1989, p. 361.

³⁴ *Medicine and Health*, January 15, 1990, reporting the Department of Commerce's prediction that health outlays will reach this number in 1990.

Witnesses testifying at the subcommittee hearing reported on the shortage of all types of health care resources in inner city areas.³⁵ Financial support for early intervention depends largely on Medicaid, private health insurance, or private income. Asymptomatic HIV-infected persons are not considered disabled and, therefore, even if impoverished, they are not usually eligible for Medicaid, and private health insurance is often inadequate for coverage of prescription drugs.

In a recent article,³⁶ Dr. Mitchell Gail and his colleagues at the National Cancer Institute (NCI) wrote that since 1987, 21 percent fewer cases of AIDS than anticipated have been reported among gay and bisexual men. This striking phenomenon was observed not only in San Francisco and New York, but throughout the U.S. However, there were no signs of such a "deficit" of AIDS cases among intravenous drug users.

According to the authors, who analyzed data from several sources, the early use of AZT as a prophylaxis by immunodeficient gay and bisexual men, possibly along with other advances in the medical care of HIV-infected, pre-AIDS patients, accounts in large part for this deficit. This finding does not imply that fewer persons are infected, only that for many immunodeficient gay and bisexual men, serious illness has been postponed. Dr. Gail and his associates pointed out that "AIDS incidence could be retarded in underserved groups, such as IVDU's, by making AZT and other state-of-the-art treatments readily available."³⁷

Thus, for those who have good access to medical care and are able to obtain AZT and other forms of preventive medicine, full-blown AIDS can be postponed. For those who are unable to avail themselves of such care, AIDS looms as a much more immediate threat. Those who are in the latter group are very often intravenous drug users, their sexual partners and their children, the vast majority of whom are black or Hispanic.³⁸

Dr. Gail wrote:

We view these preliminary findings as additional support for the treatment hypothesis and as an indication of the need to extend medical care to underserved populations. Plans should be made to deliver treatments to underserved populations and to extend treatments to a higher proportion of those populations already demonstrating AIDS deficits. Such efforts should first concentrate on providing treatment to those with severe immunodeficiency, for whom clinical benefit has been demonstrated.³⁹

At the hearing, Chairman Weiss questioned Dr. Mason about a statement attributed to him in June 1989. The statement referred to financing early intervention:

³⁵ See finding B, page 12.

³⁶ Mitchell H. Gail, Philip S. Rosenberg, and James J. Goedert, "Therapy May Explain Recent Deficits in AIDS Incidence," *Journal of AIDS*, (in press).

³⁷ *Ibid.*

³⁸ According to *HIV/AIDS Surveillance*, May 1990, published by the Centers for Disease Control, of a total of 40,544 reported AIDS cases related to intravenous drug use, 29,465 or 73 percent, were black or Hispanic.

³⁹ Mitchell H. Gail, et al., op. cit., p. 26. See footnote 36.

You said . . . that the Federal Government has a moral responsibility to determine how to pay for early intervention in HIV disease. This morning you seem to be suggesting that that's not really the role of the Federal Government.

How do you plan to carry out that moral responsibility? ⁴⁰

Dr. Mason replied:

. . . I do believe that the Federal Government does have a responsibility to determine how these things are going to be provided, but I don't think one can assume that the Federal Government will be the sole provider. I think we are all going to have to look into our back pockets: The private sector, the traditional health care financing, States, local governments, and voluntary agencies. These are big costs. I think we are going to have to work together and everyone is going to have to come up with a share. ⁴¹

But the Public Health Service has not come up with its share, nor has it led an effort to plan for the funding of early intervention. In fact, the President's fiscal year 1991 budget request eliminates all funding for the AIDS Drug Reimbursement Program, ⁴² leaving a large number of persons who have tested seropositive without a means to pay for early intervention drugs. Congress, recognizing the importance of the HHS early intervention recommendation, has taken on the Federal responsibility to assure access to life-prolonging treatments for persons who cannot afford to pay for them. The process of enacting legislation authorizing a treatment assistance program for low-income persons with HIV disease, authorizing reimbursement for HIV-related drugs, has begun. ⁴³

To explain the elimination of the drug reimbursement program, the document justifying the President's request states: "Since many private insurers and all States now pay for some HIV treatment drugs, these grants have served their purpose and no longer are required." ⁴⁴

Chairman Weiss asked Dr. Mason how PHS will determine how early intervention will be provided and financed. Dr. Mason's response was that:

Medically warranted early intervention will be paid via the traditional mechanisms in the American health care system . . . [PHS'] primary role will be in the area that I term "risk assessment." That is to say, our agencies (particularly the NIH and the FDA) will carefully evaluate all scientific developments in the area of HIV disease and,

⁴⁰ Hearing, August 1, Chairman Weiss, p. 265.

⁴¹ Hearing, August 1, Dr. Mason, p. 266.

⁴² President's Fiscal Year 1991 Budget Request.

⁴³ S. 1782, authorizing the Low-Income Treatment Assistance Program, introduced by Senator Kennedy, was folded into the "Comprehensive AIDS Resources Emergency Act of 1990," which passed the Senate in May 1990.

⁴⁴ "FY 1991 Justification of Appropriation Estimates for Committee on Appropriations," Health Resources and Services Administration, Department of Health and Human Services, Vol. I, p. 147.

based on the best available data at the time, make recommendations for the treatment and care of those infected with HIV. I expect that these recommendations will, with the assistance of CDC and HRSA, be communicated to health care professionals and HIV patients in order that informed treatment choices can be made, that take the latest therapeutic developments into account. I believe the PHS is primarily a research and prevention organization not a health care reimbursement system. . . . [Health care] is not the primary role or responsibility of the PHS—nor should it be in my judgment.⁴⁵

Dr. C. Everett Koop, former U.S. Surgeon General, recently charged that “we do not have a Federal policy on AIDS.” He said it is “incredible that the Federal government has not had a dialogue with the states, and with certain municipalities” about how the costs of the epidemic will be paid.⁴⁶ We agree.

The committee finds that the administration has not met its responsibility to plan for the funding of early intervention and other treatments for HIV disease for those who are not insured and cannot afford them. HIV-related health care, and most other health care in America, is provided according to ability to pay. Personal financial resources or private insurance lead to better care, and Medicaid coverage or no insurance at all can lead to inadequate care or no care. People who are informed, educated, and have health insurance or sufficient funds, have access to early intervention. Those who are lacking these advantages do not. PHS, as the Nation’s leading promoter and protector of the public health, has the responsibility to take the lead in developing a plan for fully funding early intervention through Federal, State and local government and private sources, and to see that it is implemented.

Once again, Congress is stepping in to protect the public health. Legislation is working its way through the House that would provide limited funds for early intervention services, and that would add poor persons with HIV infection and weakened immune systems to those covered under Medicaid.⁴⁷

B. IN MANY COMMUNITIES, THE HEALTH CARE SYSTEM IS INADEQUATELY EQUIPPED TO PROVIDE EARLY INTERVENTION TO HIV-INFECTED PERSONS

Health care systems heavily utilized by persons with HIV disease are experiencing demands for services that frequently exceed their capacity to deliver them. Caseload projections for the next few years indicate that resources will be stretched even farther if more funds are not pumped into the most needy communities. Here are some examples of the demand and its effects on health care facilities:

⁴⁵ Hearing, appendix, written response from Dr. Mason, p. 337.

⁴⁶ Dr. C. Everett Koop, statement at a hearing before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, February 27, 1990.

⁴⁷ These two bills were introduced by Rep. Henry Waxman. H.R. 4785 would provide \$500 million for early intervention services and H.R. 4080 would allow States to cover low-income persons with serious immune deficiency under Medicaid.

An average of 280 patients with HIV disease receive care each month in the outpatient clinic at Jackson Memorial Medical Center in Miami, FL. As of January 1, 1990, there was an average wait for services of six months for a new adult patient to be seen.⁴⁸

San Francisco projects that from 20,000 to 23,600 patients will require ambulatory care for HIV infection each year from 1990 to 1993. With the current capacity of a total of 45,000 patient visits annually for HIV-related diseases, the capacity for 42,000 additional patient visits per year will be required.⁴⁹

During the next five years, about 200,000 New Yorkers will need outpatient treatment for HIV disease. This will result in nearly 1 million visits per year by 1993. Currently, City hospitals provide approximately 70,000 visits per year.⁵⁰

In Boston, currently, persons with HIV disease must wait from two to six weeks for an outpatient appointment, except in an emergency. An estimated 3,000 persons with AIDS are being seen and outpatient demand will double in the next two years.⁵¹

The Parkland Hospital in Dallas has an outpatient caseload with about 1,300 visits per month. The cost of treating these HIV patients was more than \$6 million in 1989, which equals about three percent of the hospital's total operating budget.⁵²

In Baltimore, all three centers for outpatient services were reported to be at capacity, with waiting lists for new patients.⁵³

Health care providers who testified at the subcommittee hearing expressed great concern over the challenge of early intervention and their need for additional resources to support it. Problems are numerous. They described the lack of trained staff to offer early treatments; the absence of programs to teach physicians the new advances in treatment; the small number of laboratories prepared to do accurate CD4+ cell screening; the reluctance of many hospitals to begin treating AIDS patients; the use of emergency rooms for primary care. Science, they said, has outdistanced health care delivery.

Given all the progress that has been made in treatment for HIV infection, Dr. Deborah Cotton, a Boston primary care provider, finds it "ironic that at this very hopeful time those of us who care for AIDS patients are becoming painfully aware that we do not have manpower or the resources to deliver this kind of state-of-the-art therapy to people we know would benefit from it."⁵⁴

⁴⁸ Statement of Barbara King Lloyd, Administrator of the South Florida AIDS Network, Jackson Memorial Medical Center, Miami, FL, before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, February 27, 1990.

⁴⁹ "The Impact of AIDS on Cities: The Need for Emergency Relief," the United States Conference of Mayors, March 6, 1990.

⁵⁰ "Proposal for a National Response to AIDS," City of New York, September 27, 1989.

⁵¹ Op. cit. See footnote 49.

⁵² Ibid.

⁵³ *AIDS: Delivering and Financing Health Services in Five Communities*, U.S. General Accounting Office, HRD-89-120, September 1989, p. 31.

⁵⁴ Dr. Deborah Cotton, National Commission on AIDS Proceedings, November 2, 1989, pp. 155-6.

Dr. Donald E. Craven, of Boston City Hospital, testified that his AIDS clinic serves only persons with AIDS and ARC and they cannot adequately care for all these patients. They do not have the resources to treat anyone who is asymptomatic.⁵⁵

Dr. Wafaa El-Sadr testified about the obstacles to starting an early intervention program at Harlem Hospital. She said it is difficult to attract physicians and other health professionals to work with AIDS patients and to work in Harlem. Her clinic is severely understaffed even without trying to offer early intervention.⁵⁶

She also explained the need for outreach to the Harlem community once an early treatment program is in place, for patients in that area who are likely to have been exposed to HIV will not come knocking on the hospital door, as patients from more affluent communities will, even though the benefits are many. If individuals can be "captured" early in their disease, there is an opportunity for education about preventing transmission in addition to providing treatment.⁵⁷

Because of the possibility of prolonging the symptom-free period in an HIV-infected person's life, public health officials, health care providers, scientists and AIDS advocacy groups, many of whom were formerly opposed, are beginning to endorse HIV antibody testing (accompanied by pre- and post-test counseling) for all persons at risk of infection.^{58 59 60}

One leading service organization in New York City, reversing a long-held position, paid for advertisements in several New York daily newspapers that read, "If you haven't taken the antibody test for the AIDS virus—think about it, because now there are choices."⁶¹

Dr. Robert Hummel, Deputy Commissioner of Health for New Jersey, described testing as a possible gateway to treatment:

It will be necessary to change attitudes about counseling and testing. It is no longer a service that is simply educational or research oriented, but rather assumes the role as the primary entry point to care and treatment. Therefore, we need to move to a point where it is available at every single health care access point and the clinical and social services personnel are fully trained.⁶²

But witnesses questioned testing promotion when AIDS-impacted public health care systems are struggling to stay afloat and cannot provide the follow-up services. Dr. Wafaa El-Sadr spoke about this at the hearing:

. . . it is very difficult to convince our population to be tested without convincing them first that we have something for them; we have interventions that are going to

⁵⁵ Hearing, July 28, Donald E. Craven, M.D., Director, Clinical AIDS Programs, Boston City Hospital, p. 136.

⁵⁶ Hearing, July 28, Wafaa El-Sadr, M.D., Chief, Infectious Disease Section, Harlem Hospital Center, p. 145.

⁵⁷ *Ibid.*, p. 147.

⁵⁸ "Drug Said to Help AIDS Cases With Virus But No Symptoms," Philip J. Hiltz, N.Y. Times, August 18, 1989.

⁵⁹ "AZT Found to Delay Onset of AIDS; Treatment Urged for Up to 650,000," Michael Specter, Washington Post, August 18, 1989.

⁶⁰ "In Shift, Gay Men's Health Group Endorses Testing for AIDS Virus," Bruce Lambert, N.Y. Times, August 16, 1989.

⁶¹ *Ibid.*

⁶² Dr. Robert Hummel, Deputy Commissioner of Health, State of New Jersey, proceedings of the National Commission on AIDS, November 3, 1989, p. 451.

help them survive; we have interventions that will make them feel better. Unless you can convince a patient that the services are available right here for them in their community, it will be difficult to just tell them to be tested.

The testing cannot occur in a vacuum without all these services.⁶³

Dr. Nicholas Rango of New York State's AIDS Institute, testified that he supports the early intervention recommendation but its significance cannot be underestimated. In New York State alone, it is estimated that at least 60,000 persons have CD4+ cell counts warranting prophylaxis. He calls the HHS recommendations "a recipe for disaster" without a service delivery capacity to provide for all the follow-up services. These services should include, in addition to HIV counseling and testing, a full array of primary, acute, chronic, drug treatment, social, and case management services.⁶⁴

Dr. Rango charged that:

. . . The CDC announcement was phrased in such a way as to suggest that indeed it was simply a matter of testing people, doing serial CD4 counts and then introducing primary prophylaxis.

. . . the CDC announcement really obscured the central fact that what was really required was a comprehensive package of primary care . . . that would begin with a comprehensive history and physical that would stage the illness, some attention with respect to detecting comorbid States and I refer particularly to STD's, to genital ulcers and to . . . tuberculosis, and then finally . . . to substance use [and] . . . underlying mental illnesses associated with HIV, and this needs to be addressed as well in the primary care approach.⁶⁵

The committee believes that the U.S. health care system should not wait until impoverished patients are near death to treat them. Preventive therapies are available for patients with other diseases, including diabetes and hypertension. The Federal Government has an opportunity to plan rationally for providing early intervention against AIDS to persons who can benefit from it. The Committee believes that planning should begin immediately to help those who will soon develop symptoms of the disease, and to avoid the fragmented and crisis-driven policymaking that has characterized the Federal response to the AIDS epidemic from its beginning.

Government planning must address providing and coordinating ambulatory care to large numbers of new patients, the training of staff, decisions as to which medical, psychological, social and health care services will be offered, and at what locations. Early preventive primary care offers not only the opportunity to inhibit symptomatic illness, but also the opportunity to integrate prevention strategies with treatment.

⁶³ Hearing, July 28, Dr. El-Sadr, p. 145.

⁶⁴ Hearing, July 28, Nicholas Rango, M.D., Director, AIDS Institute, New York State Department of Health, p. 159.

⁶⁵ Hearing, July 28, Dr. Rango, p. 207.

Although the results of early intervention are encouraging, treatments now available do not cure AIDS or HIV infection. The committee believes that public health officials should not take the success of early intervention to mean that AIDS has, in fact, become a chronic disease similar in its management to diabetes and high blood pressure. The increasing numbers of persons with AIDS attests to the need to continue the search for better treatments and to better provide for the care of those afflicted.

C. ACCORDING TO THE ASSISTANT SECRETARY OF HEALTH, DIRECT PATIENT CARE SERVICES ARE THE LOWEST PRIORITY OF ANY AIDS PROGRAMS IN THE PUBLIC HEALTH SERVICE, IN SPITE OF THE OVERWHELMING NEED FOR RESOURCES TO ASSIST OVERBURDENED HEALTH CARE SYSTEMS

The AIDS epidemic is challenging the American health care system at its weakest points—delivery, infrastructure and financing. The 37 million uninsured persons; inadequate health care for the poor and the working poor; the special problems posed by drug users and homeless persons; the early concentration of AIDS in a few major cities—all these factors conspire to challenge the institutions that Americans depend on at times of sickness and injury.⁶⁶

At the subcommittee hearing, however, Dr. James O. Mason, Assistant Secretary for Health, told the subcommittee that paying for health care is not a Public Health Service priority:

... Over the nearly 10 years of this epidemic, we have worked closely with the President and the Congress on setting AIDS budget priorities for [the Public Health Service], and the decision that has been made jointly continues to reflect the fact that research and prevention activities are the major focus of the PHS, and I believe we have done an excellent job in these areas.⁶⁷

Later in the hearing, under close questioning by Representative Pelosi, a member of the subcommittee, Dr. Mason reiterated his earlier statement:

If you are going to ask me where I am going to put my priorities, I am going to put first priority on preventing or slowing transmission of the disease and, second, on developing therapeutics and vaccines, and then if there is money left over, we will put it into clinical services.⁶⁸

Even though Dr. Mason has declared repeatedly that direct patient care is not a function of the Public Health Service, the fiscal year 1991 budget justification for programs in the Health Resources and Services Administration (HRSA) states:

Provision of health care services to HIV infected individuals is an expanding problem. HRSA has responded by continuing its comprehensive program of service delivery

⁶⁶ Dr. Philip R. Lee, *AmFAR Report*, American Foundation for AIDS Research, Winter, 1989.

⁶⁷ Hearing, August 1, Dr. Mason, pp. 245-246.

⁶⁸ *Ibid.*, p. 275.

joined with capacity building through existing provider mechanisms and delivery sites.⁶⁹

The fact is that there have been very successful, direct health care delivery programs run by the Public Health Service for many years. The Community Health Centers, established in 1967 as providers of primary care in underserved areas, have become one of the most important components in the U.S. health care system.⁷⁰ These centers seek and receive not only Federal funds but also State and private monies and serve 500,000 to 600,000 persons in urban and rural areas across the country.

Although there are health care service programs in the Public Health Service, the lack of a Federal commitment to support AIDS primary care is reflected in the President's fiscal year 1991 budget request.

All health care services, direct and indirect,⁷¹ in PHS⁷² are conducted by the Health Resources and Services Administration (HRSA).⁷³ HRSA's staff believe \$241.5 million is needed to carry out expanded AIDS health service programs in fiscal year 1991 (\$128.5 million more than the fiscal year 1990 allocation of \$113 million).⁷⁴ But this requested amount was reduced by the Assistant Secretary of Health to \$183 million; by the Secretary of HHS to \$68 million; and by the Office of Management and Budget (OMB) to \$73 million.⁷⁵ The President's request (the OMB level) was less than one-third of the amount the agency wanted and a cut of \$40 million or 35 percent under the previous year's allocation.⁷⁶

The President's request for HRSA's AIDS programs in fiscal year 1991 is only 4.3 percent of the total PHS AIDS budget of \$1.7 billion, down from 7.0 percent of the AIDS budget in fiscal year 1990.⁷⁷

The President's budget includes \$1.1 billion for research and drug approvals at NIH, FDA and ADAMHA (Alcohol, Drug Abuse, and Mental Health Administration)—a \$79 million increase over the fiscal year 1990 appropriation for these three agencies, and \$509 million for prevention and surveillance at CDC—an increase of \$66 million over fiscal year 1990.⁷⁸ While the committee wel-

⁶⁹ "FY 1991 Justification of Appropriation Estimates for Committee on Appropriations," Health Resources and Services Administration, Department of Health and Human Services, Vol. I, p. 140.

⁷⁰ See finding G on page 26.

⁷¹ While HRSA houses all the health care delivery support programs in PHS, of those programs, only community health centers are designed to provide actual direct patient care to persons with HIV infection and AIDS. The others, such as the HIV Service Demonstration Grants, offer indirect assistance. These grants support coalitions of health care and social service providers working with community organizations. The grants have been helpful, but are small and limited in purpose, and they are demonstration grants, slated to be reduced and ultimately terminated.

⁷² A discussion of Medicaid and Medicare expenditures for AIDS patients is not included in this section of the report. These two entitlement programs reimburse hospitals and health care providers for specific health care services supplied to patients. They are administered by the Health Care Financing Administration which is not a part of the Public Health Service. See page 5 of this report for a description of Medicaid and Medicare and pages 30 through 35 for findings related to Medicaid.

⁷³ See "Introduction" section of this report for a description of HRSA AIDS health care service programs, pp. 4-5.

⁷⁴ From PHS documents submitted to the subcommittee in response to a request from Chairman Weiss. In subcommittee files.

⁷⁵ Ibid.

⁷⁶ Ibid.

⁷⁷ *Budget of the United States Government, Fiscal Year 1991.*

⁷⁸ Ibid.

comes these increases for the other agencies, modest though they may be, we believe the slashing of the HRSA budget is unnecessarily severe.

In answer to a question at the hearing about the dichotomy between the scientific advances in treatment and care and the budgetary responses to those advances by the Administration, Dr. Samuel Matheny, HRSA's Associate Administrator for AIDS, told the subcommittee that:

. . . Our budget for [AIDS] health care delivery is four percent of the Public Health Service [AIDS] budget. I think that speaks for itself.⁷⁹

The committee finds that the Federal Government (though inadequately) has provided for AIDS research, prevention of HIV transmission, testing for HIV, and counseling before and after testing. But it has not anticipated nor attempted to meet the need to support health care delivery systems to provide primary medical services to people infected with HIV.

D. AIDS HAS EXACERBATED EXISTING PROBLEMS OF OVERBURDENED, UNDERSTAFFED, UNDERFUNDED HOSPITALS

City hospitals are the "providers of last resort" for millions of poor city dwellers across the country who have no where else to turn for medical or social services.⁸⁰ The patient load is heavy and these hospitals are not receiving the funds nor do they have the personnel to handle it.⁸¹

Among the reasons for these problems are the increasing numbers of AIDS patients, the growing proportion who are poor, the drug epidemic, the lack of alternate care facilities—including nursing homes and hospices—willing or able to take persons with AIDS, insufficient reimbursements from Medicaid and the lack of private health insurance.

The concentration of the Nation's AIDS patients in cities across the country is causing severe financial problems for hospitals, reducing access to care and lowering quality standards. As a result, patients with other illnesses who also need care are shut out.

For example, Dr. Lewis Goldfrank, director of emergency medicine at New York's Bellevue Hospital Center, maintained that patients "are crowding into our corridors, our waiting rooms and our treatment areas. . . . Over the last six months, most of our [public] hospitals have faced changing census patterns that make bed accessibility for the next patient impossible."⁸²

Last year, there were from 100 to 600 AIDS patients in New York City hospitals each day because alternative services were not available. This problem could quadruple by 1994 if long term and ambulatory AIDS care are not expanded.⁸³

⁷⁹ Hearing, August 1, Samuel C. Matheny, M.D., Associate Administrator for AIDS, Health Resources and Services Administration, Department of Health and Human Services, p. 315.

⁸⁰ "Metropolitan Hospitals: An Urban Tug of War," *Medicine and Health Perspectives*, May 21, 1990.

⁸¹ *Ibid.*

⁸² "Emergency Rooms Overwhelmed as New York's Poor Get Sicker," *The New York Times*, December 19, 1988, as quoted in *Crisis at the Front Lines: The Effects of AIDS on Public Hospitals*, A Twentieth Century Fund Paper, Dennis Andrulis, New York, 1989, p. 9.

⁸³ AIDS Task Force of the Mayor, New York City, March 1989.

The largest city hospitals in the United States are carrying the greatest burden of AIDS care. In 1987, 276 acute-care hospitals responded to a survey by the National Public Health and Hospital Institute (NPHHI) on their inpatient and outpatient AIDS care. NPHHI found that only 20 percent of the hospitals provided 77 percent of AIDS patient care, and just 5 percent of the hospitals were providing 50 percent of the care.

NPHHI also found that inpatient costs at the hospitals averaged \$681 per day, while revenues were an average of 80 percent of costs at \$545 per day. Losses were significantly higher at public hospitals (an average of \$218 per day) than at private facilities (averaging \$92 per day).⁸⁴

One of the major sources of ambulatory care for persons with HIV disease is the hospital outpatient clinic. The NPHHI survey found the average cost of a clinic visit by a patient with HIV disease was \$237, but Medicaid reimbursements averaged only \$63, or 27 percent of costs. This payment ratio was much lower than the 72 percent average reimbursement per visit for non-AIDS outpatient services.⁸⁵ Only 22 of the hospitals surveyed by NPHHI provided information on the cost of AIDS care, but for those hospitals, losses for inpatient and outpatient services combined totaled more than \$23 million during the year of the survey.⁸⁶

The NPHHI survey results are distressing, and the problems they highlight have not doubt worsened since the data were collected in 1987. Since then the number of AIDS cases has increased dramatically,⁸⁷ with increasing incidence among low-income Americans. The study did not include data on patients with HIV disease that had not progressed to full-blown AIDS but required treatment. A 1989 study by the General Accounting Office described a further cause of concern. The study reported, "it is important to stress that the burden of HIV disease on health delivery . . . systems greatly exceeds that of the AIDS cases that are reported as meeting CDC's surveillance case definition."⁸⁸ Consequently, as health care providers discuss the effects of the epidemic on their hospitals and other facilities in terms of reported cases, the effect of the epidemic could very well be underrepresented.

According to the NPHHI, "the financial story is a grim one. The costs of AIDS are high, the revenues do not meet the costs, and the sources of funds are drying up."⁸⁹ In some instances, hospitals that were caring for large numbers of indigent patients before AIDS struck have now been saddled with additional financial burdens—increasing numbers of AIDS patients with insufficient Medicaid payments or no payments at all.

Again, from the NPHHI survey:

⁸⁴ Dennis P. Andrulis, Virginia Beers Weslowski, Larry S. Gage, "The 1987 US Hospital AIDS Survey," *Journal of the American Medical Association*, August 11, 1989, Vol. 262, pp. 784-794.

⁸⁵ *Ibid.*

⁸⁶ *Op. cit.*, p. 33. See footnote 82.

⁸⁷ The cumulative number of cases reported to the CDC from the beginning of the epidemic in 1981 through 1987 was 65,119. In 1988 and 1989, 52,662 additional cases were reported. From *HIV/AIDS Surveillance Report*, Centers for Disease Control, January 1990.

⁸⁸ *AIDS: Delivering and Financing Health Services in Five Communities*, GAO/HRD-89-120, U.S. General Accounting Office, September 1989.

⁸⁹ *Op. cit.*, p. 35. See footnote 82.

In 1987, out of a reported 7,543 [outpatient] visits, 64 percent were self-pay visits, 24 percent were covered by Medicaid, 10 percent were covered by private insurance, and the remaining 2 percent were Medicare visits. The alarmingly high proportion of self-pay or no-pay visits points to a significant problem for public hospitals. Clearly, there is currently no financial incentive for these institutions to provide more outpatient care, even if such care is more cost-effective and more appropriate for the patient.⁹⁰

Personnel shortages also compromise the ability of hospitals to offer adequate care. The care of AIDS patients is labor intensive. Dr. Paul Volberding, chief of the AIDS Program at San Francisco General Hospital, testified at the hearing about another difficulty confronting hospitals—the shortage of trained health care professionals to work in hospital settings:

The expanding epidemic certainly requires a parallel expansion in the number of health care providers. Yet, little, if anything, is being done to ensure that this is taking place. Training is haphazard at all levels with little coordination of AIDS education in medical student curricula and little, if any, formal inclusion in specialty and subspecialty training programs. Organized medical groups are still reluctant to require continuing medical education in any area, including AIDS, and what little training program support is available is concentrated at providing only entry level information in the form of one to two day workshops.⁹¹

According to the Conference of Metropolitan Hospital Associations, the inability of city hospitals to recruit and retain qualified staff “strikes at the heart” of their capacity to serve their target population.

The problem of hospital care for AIDS has moved well beyond the hardest hit cities such as New York and San Francisco. Hospital administrators in Kansas City, MO; Memphis, TN; Dallas, TX; Westchester County, NY; and Pontiac, MI, joined the NPHHI to signal their concern over the problems brought to their facilities by the epidemic.⁹² Reports of patients overflowing from urban hospital emergency rooms into adjacent hallways are now also heard in Miami, Dallas, Atlanta, and other cities.⁹³ The predicament that hospitals across the country are facing places this issue on the national agenda.

At Truman Medical Center in Kansas City, MO, AIDS care averages \$7,500 per patient, but Medicaid reimbursements average \$2,100 per patient.⁹⁴

⁹⁰ Ibid., pp. 36–37.

⁹¹ Hearing, August 1, Paul A. Volberding, M.D., Associate Professor of Medicine, University of California, San Francisco, and Chief, AIDS Program, San Francisco General Hospital, p. 229.

⁹² “Concentration of AIDS Cases Posing Serious Problem for Some Hospitals,” Bruce Lambert, New York Times, August 11, 1989.

⁹³ “The Impact of AIDS Upon America’s Cities,” *AIDS Information Exchange*, U.S. Conference of Mayors, Vol. 7, April 1990.

⁹⁴ *The Health of Urban America*, Conference of Metropolitan Hospital Associations, 1990.

Miami's Jackson Memorial Hospital had a deficit, just from AIDS care, that was \$3 million in 1988, climbed to \$6 million in 1989, and is expected to reach \$12 million this year. Jackson cares for about 1,600 AIDS patients a year. The services are estimated to average \$30,000 for each AIDS patient.⁹⁵

In San Juan, Puerto Rico, more than 70 percent of all AIDS patients who use the public hospital system are indigent, unemployed, and IV drug users.⁹⁶

E. PROVIDERS OF AIDS CARE ARE FORCED TO RELY ON TEMPORARY DEMONSTRATION FUNDS, MULTIPLE GRANT APPLICATIONS AND INADEQUATE FINANCING TO CONDUCT FRAGMENTED PROGRAMS FOR THEIR HIV-INFECTED PATIENTS

In February 1989, at the subcommittee's hearing on pediatric AIDS, several health providers described the problems they confront in trying to deliver services to women, children, and families affected by HIV disease. They spoke about fragmentation of services, never-ending grant applications, the need to use Federal research funds to provide services, and the continual shortage of funds and staff. One witness put it this way: "We at Harlem [Hospital] are managing to . . . meet the tremendous needs of our families with . . . spit and baling wire."⁹⁷ A second witness expressed her anguish: ". . . we are strapped for resources, we are short staffed, we face enormous provider burnout, and are functioning within the well known and documented crisis of New York City's overburdened hospitals and emergency rooms. . . ."⁹⁸

These problems were also reported at subcommittee hearings in Washington, DC, San Francisco, New York, Newark, and Detroit in 1987 and 1988.⁹⁹ The problems of those providing services to AIDS patients and their families have only worsened since then. Several witnesses at the 1989 hearings spoke of time lost from patient care by health care professionals who are required repeatedly to write grant applications for programs that provide only temporary funding:

What happens when [our] grants end? At the present time, a good 50 to 60 percent of my time and that of my colleagues is spent trying to find funds to plug the holes in a public health care system that has long been ignored. AIDS has not created the holes. It has just blown apart a structure that has been allowed to deteriorate from neglect.¹⁰⁰

⁹⁵ "AIDS: Moving Toward Chronic Care," *Medicine and Health Perspectives*, March 20, 1989.

⁹⁶ Op. cit. See footnote 93.

⁹⁷ Hearing on "Children and HIV Infection," Human Resources and Intergovernmental Relations Subcommittee, Committee on Government Operations, U.S. House of Representatives, February 22, 1989, Dr. Janet Mitchell, Chief of Perinatology, Department of Obstetrics and Gynecology, Harlem Hospital Center, New York City, p. 26.

⁹⁸ Ibid. Joanne E. Lukomnik, M.D., Medical and Executive Director, Comprehensive Family Care Center, Albert Einstein College of Medicine, Bronx, NY, p. 47.

⁹⁹ Hearings before a subcommittee of the Committee on Government Operations, U.S. House of Representatives, "The AIDS Crisis in Two American Cities," September 18, 1987, and November 23, 1987; "The AIDS Epidemic in Newark and Detroit," March 27, 1989, and April 24, 1989; and "Children and HIV Infection," February 22 and 23, 1989.

¹⁰⁰ Hearing on "Children and HIV Infection," op. cit., Dr. Mitchell, p. 27. See footnote 97.

... at this time, what funding is available from all sources, Federal, State, and city, is on a competitive demonstration grant basis with limited objectives and goals. In addition to requiring enormous energy and time from health care service providers in preparing proposals for these grants, this type of grant funding allows for no stability of service. It creates a form of medical anarchy in which each of us tries to find the magical set of words which will provide a year or two of limited funding for a slice of necessary services in the form of a demonstration.¹⁰¹

... we're exhausted from writing grants. My family can't take it any longer. I spend probably 20 weekends a year, plus many evenings, doing nothing but writing grants. Furthermore, it means that I'm not available to provide care and I'm not talking [just] about myself but myself multiplied hundreds and hundreds of times over.¹⁰²

[A colleague] ... testified during previous hearings about the increasing time health-care delivery providers must spend on grant writing rather than on delivering medical care. This assumes they can determine what these diverse grant programs are. Generally, only the health-care delivery programs with the largest budgets apply because they can afford grant writers. But many such delivery systems are not geared to serve the indigent or other individuals at greatest risk of contracting AIDS. Frequently, the community-based delivery systems that serve the indigent, drug addicts, their sexual partners and their children are less successful in obtaining funding.¹⁰³

Witnesses at the hearings also criticized the absence of Federal and other sources of funding for service delivery. In many instances, research funds must be used for patient care. Here are some of the statements:

The problem [of AIDS care] is worsened by the lack of available health and social services in our communities. While dollars are available for various research and education activities, little funding has been directed to service delivery. The first specific [Federal] funding for children, the pediatric AIDS demonstration programs, began in 1988, 5 years after HIV infection was reported in children.¹⁰⁴

... much of the dollars that are budgeted for research are going for service and that research is becoming the infrastructure in many of our communities for service.¹⁰⁵

... Funding service through research grants is probably the worst possible way to fund service delivery. Not only

¹⁰¹ Ibid., Dr. Lukomnik, p. 49.

¹⁰² Ibid., Dr. Lukomnik, p. 60.

¹⁰³ Hearing, July 28, David Smith, M.D., Medical Director, Community Oriented Primary Care, Parkland Memorial Hospital, Dallas, TX, p. 130.

¹⁰⁴ Hearing, "Children and HIV Infection," op. cit., testimony of Mary G. Boland, M.S.N., Director, AIDS Program, Children's Hospital of New Jersey, Newark, NJ, p. 34. See footnote 97.

¹⁰⁵ Ibid., Ms. Boland, p. 58.

does it mean that in many cases you can't do the research you want to do, it means that you can't really offer the services you want to offer because you have to twist your grants in such a way as to allow for the occasional social worker or case manager . . .¹⁰⁶

The committee finds that the present system of temporary short-term grants and categorical demonstration programs is so fragmented that it is very difficult to provide a continuum of care. The system places too great an administrative burden on health care providers, and does not accommodate the patient. A solution must be found that has as its primary focus the patient, the family, and those at greatest risk.

Dr. David Smith, Medical Director of a community care program at Parkland Hospital in Dallas, presented several recommendations at the hearing that the committee finds essential if patients with HIV disease are to receive adequate, compassionate, comprehensive care, oriented toward their needs:

Simplify or eliminate the diffuse grant-application process. Avoid the concept of demonstration grants when dealing with service delivery because they require a constant search for refunding. They are for a limited time and do not allow for the long-term needs of AIDS patients.

Make a commitment to fund and support comprehensive primary medical care for AIDS patients. Allocated funds must support continuity of care. We must make it easier for patients to enter and remain in the health care delivery system.

Urge coordination of [P]ublic [H]ealth [S]ervice efforts and resolve current inter-agency and intra-agency barriers. Eliminate duplicate programs. . . .

Require the comprehensive primary care programs for HIV patients to demonstrate a continuum of care. It should take the patients from early intervention through a hospital stay and home again. A model already exists in this country to do this. It is our current decentralized oncology model. Cancer patients can remain in their community for care and chemotherapy, but more importantly remain within their family-support structure. This model works with cancer patients who are just as ill as AIDS patients.¹⁰⁷

F. AIDS IS A NATIONAL DISASTER THAT CAN DEVASTATE A COMMUNITY AS MUCH AS AN EARTHQUAKE OR A HURRICANE. AIDS-IMPACTED AREAS SHOULD RECEIVE FEDERAL EMERGENCY RELIEF FUNDS SIMILAR TO FEDERAL DISASTER ASSISTANCE MADE AVAILABLE TO LOCALITIES AFFECTED BY OTHER KINDS OF DISASTERS

Within 3 days of the recent San Francisco earthquake, the Federal Government had awarded several billion dollars to the city for disaster assistance. Many billions of dollars have been committed to bail out the savings and loan industry. But no such response to

¹⁰⁶ Ibid., Dr. Lukomnik, p. 60.

¹⁰⁷ Hearing, July 28, Dr. Smith, pp. 131-132.

AIDS has been made, even though thousands of human lives have been lost and thousands more will die.

When a community is ravaged by a hurricane or flood, a wide range of Federal assistance is available and the funds usually reach the affected localities without delay.¹⁰⁸ State and local governments are not expected to shoulder the total burden of protecting public health and rebuilding property. The committee believes that AIDS is no less a national disaster than a hurricane or an earthquake and that the same level of Federal commitment should apply when a public health emergency strikes a locality. Federally-funded disaster assistance should be offered to communities hardest hit by the AIDS epidemic.

Witnesses at the subcommittee hearing from San Francisco and New York spoke out on the desperate condition of not only their own areas' AIDS services but others as well. Patricia Christen, Executive Director of the San Francisco AIDS Foundation said:

... Cities like San Francisco, New York, Newark, Miami, Ft. Lauderdale, Atlanta, Washington, Los Angeles, and other epicenters of this disease need to be considered natural disaster areas and be eligible for the type of emergency funding we would afford a drought in Kansas, an oil spill in Alaska, or a flood in Texas.¹⁰⁹

The San Francisco model is known worldwide as a highly successful approach to providing optimum non-acute care to persons with AIDS. It depends on a variety of case-managed home and community-based services, provided by health care professionals and supported by large numbers of volunteers. But according to Dr. Paul Volberding, Chief of the AIDS Program at San Francisco General Hospital, the increased number of patients, ongoing problems with reimbursement, increasing fragmentation of services, and the need for more trained health care personnel are placing the San Francisco model under great stress.¹¹⁰

New York City, on the other hand, with nearly 20 percent of all AIDS cases in the United States, has a decaying health care system close to breakdown. More than 25,000 New Yorkers have developed AIDS during the past 10 years and over 15,000 have died.¹¹¹ AIDS is now the leading cause of death among men aged 30 to 44, women between the ages of 25 and 39, and children from one to four years old in New York City.¹¹²

NORA, a coalition of National Organizations Responding to AIDS, includes nearly 100 mainstream groups committed to developing comprehensive, humane, effective Federal AIDS policies. The coalition has for some time supported the development of disaster assistance targeted on jurisdictions that include not only hard-hit

¹⁰⁸ *Disaster Assistance Programs*, a digest of Federal disaster assistance programs, published by the Federal Emergency Management Agency, June 26, 1989, lists more than 80 programs funded by the Federal Government that support relief and recovery efforts following major disasters or emergencies.

¹⁰⁹ Hearing, July 28, Pat Christen, Acting Executive Director, San Francisco AIDS Foundation, p. 171.

¹¹⁰ Hearing, August 1, Dr. Paul Volberding, p. 224.

¹¹¹ *AIDS Surveillance Report*, New York City Department of Health, April 25, 1990.

¹¹² Conversation with Ellen Rautenberg, Associate Commissioner of Health, New York City Department of Health, May 30, 1990.

cities such as New York and San Francisco, but reach beyond those cities to New Haven, Houston, Boston, Miami, Newark and many others.¹¹³

At the hearing, Jean McGuire, Chair of NORA, expressed the frustration of many of the witnesses at the lack of Federal funds for AIDS patient care:

I listened [at the hearing] with our front-line providers, with Harlem Hospital, with Parkland [Hospital]. . . . How much worse can it get? How much worse a picture has to be painted?

. . . how do we create the sense of urgency that we need?¹¹⁴

Ms. McGuire described one possible program. Disaster assistance would be targeted to jurisdictions with relatively high rates of HIV infection. A continuum of hospital and ambulatory services would be offered, as well as home health care and sub-acute care. Any disaster assistance program would be prohibited from supplanting State or local funds that are or would otherwise be obligated to finance these services. The Secretary of HHS would report to Congress annually regarding the performance of programs funded under this proposal. Since a significant portion of the services described here have been provided by community-based organizations, they would be high on the list of recipients of any available funds.¹¹⁵

Once again, it is the Congress that has recognized the need and acted on it. A bill with bipartisan support, the Comprehensive AIDS Resources Emergency Act of 1990 (CARE), was adopted by the Senate in May 1990.¹¹⁶ A bill containing similar provisions passed the House in June.¹¹⁷ Both bills would provide emergency relief funds for hardest hit cities and States.

The assistance such a program would provide would go beyond AIDS; it would help to reinforce the infrastructure of health care for poor Americans in those communities that are funded, and indirectly provide assistance to health facilities used by all persons in the area.

In answer to a written question about a Federal disaster assistance program submitted by Chairman Weiss, Dr. Mason, Assistant Secretary for Health, responded:

The need for [disaster assistance] . . . is being addressed to a substantial extent by current Federal programs. The Health Resources and Services Administration HIV services grant programs have a service component for areas of high AIDS prevalence and a planning grant component for areas of lower prevalence. The intent of these programs is to facilitate the integration of community resources into a comprehensive and coordinated system of care for HIV-in-

¹¹³ Hearing, July 28, Jean F. McGuire, Executive Director, AIDS Action Council, pp. 196-197.

¹¹⁴ *Ibid.*, p. 210.

¹¹⁵ *Ibid.*, pp. 196-197.

¹¹⁶ S. 2240, Comprehensive AIDS Resources Emergency (CARE) Act of 1990, introduced by Senators Edward Kennedy and Orrin Hatch.

¹¹⁷ H.R. 4785, The AIDS Prevention Act of 1990, introduced by Representative Henry Waxman.

fected people. It is anticipated that these systems of care will lend themselves to replication in other communities with funding from the private sector or State or local government sources.¹¹⁸

However, the level of funding for the programs Dr. Mason described in fiscal year 1990 is \$17 million and the Administration requested only \$19.4 million for fiscal year 1991, hardly enough to meet the needs of impacted cities. The CARE bill authorizes \$600 million, still a conservative amount. The committee finds that neither the funding levels nor the program design for HIV Services Demonstration Grants begin to approximate what is needed to provide adequate disaster assistance to our Nation's troubled cities plagued with the AIDS epidemic.

The cost of emergency assistance to communities suffering from the unexpected disasters of drought, flood, or oil spill is carried by the U.S. population as a whole through congressional appropriations for emergency relief programs. The committee believes that similarly, a more substantial portion of the cost of AIDS should be borne by the entire Nation through a disaster assistance program.

G. COMMUNITY AND MIGRANT HEALTH CENTERS, THE LARGEST AND LONGEST SURVIVING PRIMARY CARE FACILITIES FUNDED DIRECTLY BY THE FEDERAL GOVERNMENT, ARE ON THE FRONT LINES OF THE AIDS EPIDEMIC AND NEED MORE SUPPORT

Community Health Centers (CHC's) are strategically located in medically underserved areas where the AIDS epidemic is flourishing, or will likely spread in the future. The program is founded on the principle that health care must be provided in a manner culturally and ethically acceptable to its clients. For this reason, each CHC is governed by a board, the majority of whose members are community residents served by the center.¹¹⁹

There are about 550 CHC's which provide primary care to an estimated 5.4 million persons across the country.¹²⁰ At many centers, the patient population includes substantial numbers of persons at risk for HIV infection. The National Association of Community Health Centers (NACHC) estimates that in 1989, 55,000 of all CHC clients were HIV-infected. If you add the estimated homeless population who are HIV-infected and served by CHC's, the total seropositive caseload reached approximately 66,000 in 1989. The projections for 1990 and 1991 are 75,000 and 90,000 infected persons, respectively.¹²¹

The centers offer a comprehensive spectrum of primary care services and have linkages to other health care providers for additional services. If there is a demand for HIV-related services in the area near the CHC, and if the CHC has the resources to provide the services, it can play an important role in meeting the needs of the HIV patient for ambulatory care.

¹¹⁸ Hearing, appendix, p. 331.

¹¹⁹ Public Health Service Act, Section 330(e)(3)(G).

¹²⁰ "FY 1991 Justification of Appropriation Estimates for Committee on Appropriations," Health Resources and Services Administration, Department of Health and Human Services, Vol. I, p. 68.

¹²¹ "Primary Care Costs in AIDS (Annual) for C/MHC-HCH," National Association of Community Health Centers, August 21, 1989.

Ideally, these centers should be providing the full spectrum of AIDS care, including HIV testing, counseling, early detection and treatment, post-hospital discharge care, and other services. But to take on this monumental task, community health centers need better funding, more doctors and nurses, and better support services.¹²²

The Center for Health Policy Studies conducted a study of the impact of the HIV epidemic on community health centers for the New York State Health Department. The study showed that the number of HIV-infected clients in the State's centers at the time of the study was low, even though results confirmed that the CHC's were ideal candidates to provide primary care to the HIV-infected population due to their location, service to high risk groups and linkages to other primary care organizations.¹²³

Testifying at the hearing, Dr. Nicholas Rango, director of the New York State AIDS Institute made the point that:

While a strong commitment and integration of community health providers in HIV care would be ideal, community health centers in New York State have, for the most part, not developed the capability to provide primary care services that address the needs of the HIV-infected substance abuser.¹²⁴

In fact, according to the New York State study, "the centers expressed a reluctance to being 'designated' for HIV treatment."¹²⁵ This is due, in large part, to the lack of resources available to the CHC's. Medicaid reimbursement rates do not adequately pay for covered services and in many States do not pay for case management, or other cost-effective services. But, according to Dr. Rango, the larger problem for the CHC's, at least in New York, is the indigent patient population that is "below private insurance and above Medicaid."¹²⁶

Dr. Donald Craven of Boston City Hospital supported Dr. Rango's views in discussing the situation at Boston:

. . . They are trying to get community health centers . . . involved in caring for [people with HIV infection]. . . . It is very, very difficult because [the centers] . . . are very financially strapped. They are a very needy population. . . . [CHC's] don't have the resources . . . so it is very hard to convince people in the community health centers to actually get involved with AIDS. Their natural tendency is to try to pull back from AIDS . . . because of . . . resources that they don't have and financial reimbursements that they often don't get.¹²⁷

¹²² Dr. Si-Hoi Lam, Hill Haven Health Center, New Haven, CT, proceedings of the National Commission on AIDS, November 3, 1989, p. 461.

¹²³ *Study of the Impact of the HIV Epidemic on Community Health Centers in New York State, Final Report*, Center for Health Policy Studies, June 26, 1989 (draft).

¹²⁴ Hearing, July 28, Dr. Rango, p. 165.

¹²⁵ Center for Health Policy Studies, op. cit., p. 6-5. See footnote 123.

¹²⁶ Hearing, July 28, Dr. Rango, p. 214.

¹²⁷ Ibid., July 28, Dr. Craven, p. 152.

In fact, the New York State study described above reported that 27 percent of the HIV-infected clients seen in the CHC's surveyed were indigent, and went on to say:

This finding, combined with the finding that it is more expensive for health centers to serve HIV patients than other patients, indicates that as the number of HIV patients served by health centers increases the financial burden on them will also increase disproportionately. As a result, in the absence of other sources of support, grant funding to specifically subsidize the medical care of HIV patients will become necessary.¹²⁸

Dr. Rango argued that only underwriting the cost could assure care for indigent patients:

One of the things that must happen to get the freestanding community health centers to provide the primary care that they want to provide, they are ideally located to provide, is to pick up that indigent financing piece.

New York State has covered the Medicaid, sir. But, when are the Fed's going to cover the indigent piece?¹²⁹

The "Fed's" did, in fact, appropriate \$10.9 million specifically for community health center clients with HIV disease in fiscal year 1990. The administration's fiscal year 1990 budget justification stated that this amount would serve 4,500 of the estimated 75,000 HIV-infected CHC clients and provide support for 54,600 "medical encounters" or office visits.¹³⁰

For fiscal year 1991, HRSA originally requested \$36 million specifically for HIV care in Community Health Centers, but it was whittled down by the Assistant Secretary for Health, the Secretary, and OMB to \$13.4 million, which, according to HHS' budget documents, will "serve" a total of 38,200 HIV-infected patients out of the 90,000 estimated for 1991.¹³¹ But NACHC's figures suggest it would take \$100 million to serve 38,200 patients, not including therapeutic drugs.¹³²

The allocation of \$13.4 million for AIDS care is far from the amount needed to get the community health centers appropriately involved in serving persons with HIV infection. NACHC estimates that if all 66,000 seropositive clients had been cared for in 1989, it would have cost \$483 million, including chemoprophylaxis. If the high price of therapeutic drugs is factored out, the cost would have been \$173 million. The numbers would be much higher for 1990 and 1991.¹³³

The CHCs' need for additional funds for AIDS and HIV care is especially desperate since the base appropriation for community health centers has not kept up with the growth in caseloads or new financial demands. The past few years have not brought prosperity

¹²⁸ Center for Health Policy Studies, *op. cit.*, p. 6-7. See footnote 123.

¹²⁹ Hearing, July 28, Dr. Rango, p. 214.

¹³⁰ "Fy 1991 Justification of Appropriation Estimates for Committee on Appropriations," Health Resources and Services Administration, Department of Health and Human Services, Vol. I, p. 142.

¹³¹ HRSA's budget request to the Public Health Service, May 25, 1989.

¹³² *Op. cit.* See footnote 121.

¹³³ *Ibid.*

to CHC's. The funding level has grown by only \$8.5 million from fiscal year 1987 to the fiscal year 1990 appropriation of \$428 million.¹³⁴

And yet the past decade has brought the centers the increasing need for expensive malpractice insurance; the decline in the number of National Health Service Corps physicians and nurses, and the resulting need to offer higher staff salaries; the deterioration of overall health status of CHC clients, due in part to the cuts in Federal "safety net" programs for the poor during the Reagan administration; and, of course, the exploding drug addiction and AIDS epidemics.¹³⁵

Dr. Mason, the Assistant Secretary for Health, in responding to Chairman Weiss' inquiry about the need for additional funds for CHC's to meet the challenge of the epidemic, stated the administration's position:

. . . [The centers] are continually encouraged to assist clients/users in getting Medicaid coverage and maximizing 3rd party reimbursement wherever possible. Centers are also advised to develop strong referral arrangements. In addition, centers are encouraged to solicit funding from State, local and philanthropic sources.¹³⁶

In other words, the CHC's should look outside the Federal Government for funds to supplement either the base allocation for CHC's or additional funds for indigent HIV patients.

It is interesting to note that, in spite of the Assistant Secretary's statement, the fiscal year 1991 justification of the CHC services for AIDS makes a persuasive case for targeting resources on primary care for HIV-infected patients:

Currently, available services in many communities for persons with AIDS/HIV infection are relatively uncoordinated, fragmented, and often very expensive. Reimbursement for these services is variable and may be inadequate, particularly for out-of-hospital care, since a large and growing number of persons with AIDS are also poor and medically uninsured, or are persons covered only by Medicaid or other forms of public assistance. If a wider range of community-oriented, coordinated, ambulatory health care is available, hospital costs and possibly other related costs could be decreased. Focusing resources on outpatient services, home health care, or hospice care is likely to improve continuity and reduce the cost of HIV/AIDS patient care.¹³⁷

The committee finds itself in agreement with HHS' statement, but not with HHS' intransigence. For the reasons presented in the

¹³⁴ Conversation with staff of Subcommittee on the Departments of Labor, Health and Human Services, and Education, Committee on Appropriations, U.S. House of Representatives, March 14, 1990.

¹³⁵ Conversation with David Cavanaugh, Research Specialist, National Association of Community Health Centers, May 31, 1990.

¹³⁶ Hearing, appendix, p. 354.

¹³⁷ "FY 1991 Justification of Appropriation Estimates for Committee on Appropriations," Health Resources and Services Administration, Department of Health and Human Services, Vol. I, p. 142.

statement above, the committee believes the base funding for Community Health Centers, as well as funding expressly for HIV-related services, must be sharply increased, given the magnitude of the epidemic and the expanding role community health centers are being called on to play.

H. THE MEDICAID PROGRAM DOES NOT COVER MANY ESSENTIAL SERVICES FOR HIV PATIENTS NOR DOES IT REIMBURSE FOR THE FULL COST OF CARE FOR THOSE SERVICES THAT ARE COVERED

Health care expenditures for a typical AIDS patient range from \$24,000 to \$147,000.¹³⁸ Most recent estimates are closer to \$75,000.¹³⁹ The total cost of personal care for individuals with HIV disease has been estimated at \$5.3 billion in 1991.¹⁴⁰ However, AIDS care is less than 1 percent of the total U.S. health care budget.

In fiscal year 1989, Medicaid covered 25 percent of all direct health care costs for AIDS patients with a cost to the Federal Government and the States¹⁴¹ of \$950 million.¹⁴² By 1993, this figure is likely to reach \$2.5 billion.¹⁴³

These considerable expenditures for Medicaid are inaccurate harbingers of future AIDS care costs. Variables include the cost of new therapies, which could, in turn, improve survival rates, and future epidemiologic trends, especially the spread of AIDS among intravenous drug users and their sexual and needle-sharing contacts.

Even so, it is important to view the financial impact of AIDS care on Medicaid in perspective. AIDS spending is estimated to be only 2.5 percent of the Federal share of Medicaid by fiscal year 1993.¹⁴⁴ HCFA predicts that these costs would continue to increase during the 1990's, but would remain a relative fraction of Federal Medicaid costs, perhaps reaching 6 percent by the end of the decade.¹⁴⁵

Nationally, the Medicaid Program provides coverage of services for 40 percent of all AIDS patients. In some areas such as New York and New Jersey, this is as high as 65 to 70 percent. However, Medicaid does not pay for all the cost of care for those patients who are covered. Patients may become Medicaid eligible after already receiving some treatment; Medicaid may not cover the entire cost of their treatment; there may be a lag between Medicaid incurrence of costs and eligibility; Medicaid reimbursement rates are usually much lower than actual costs of treatment (especially true

¹³⁸ "The Cost of AIDS and Other HIV Infections: Review of the Estimates," Office of Technology Assessment Staff Paper, U.S. Congress, May 1987.

¹³⁹ "Updated Forecasting of the Costs of Medical Care for Persons with AIDS, 1989-93," Fred J. Hellinger, *Public Health Reports*, Vol. 105, January-February, 1990, p. 1.

¹⁴⁰ *Ibid.*

¹⁴¹ The Federal Government pays about 55 percent of U.S. Medicaid costs; the States pay the rest.

¹⁴² "AIDS Cost Estimates," Note to Patsy Fleming from Nancy Dapper, Health Care Financing Administration, Department of Health and Human Services, February 9, 1990.

¹⁴³ *Ibid.*

¹⁴⁴ *Ibid.*

¹⁴⁵ William Roper and William Winkenwerder, "Making Fair Decisions About Financing Care for Persons with AIDS," *Public Health Reports*, Vol. 103, May-June, 1988, pp. 305-306.

for outpatient treatment); and persons with Medicaid may receive different services from patients with other types of coverage.¹⁴⁶

Although Medicaid is the largest single payer for the health care of persons with AIDS in the United States, many HIV-infected poor individuals do not qualify. Along with poverty, the gateway of eligibility into Medicaid is a determination of disability. Only persons with advanced ARC or AIDS, as defined by CDC, are considered to be disabled. The Medicaid Program is designed so that an HIV-infected, non-disabled, single adult or a childless couple between the ages of 22 and 64, are not eligible, no matter how poor they are. Nor are they eligible for Medicare, which is limited to the aged and disabled. If they were disabled, they would have to wait two years to receive benefits, once disability was established.¹⁴⁷

The share of AIDS care costs paid by Medicaid, already the largest among payment sources, has increased in the last few years. A study of hospital discharges in California and New York found a distinct trend away from privately supported health insurance toward Medicaid among persons with AIDS from all racial and ethnic groups from 1983 to 1986. One likely explanation for this shift is that the loss of employment, the loss of private insurance and the impoverishment that follows, drive persons with AIDS to Medicaid. Another is the increasing proportion of IVDU's with AIDS. They are more often covered by Medicaid than persons who practice other risky behaviors because they are more likely to be poor.¹⁴⁸

The trend toward Medicaid coverage has implications for AIDS primary care. One effect is lower quality of care.¹⁴⁹ In many areas, physician reimbursement rates are so low that patients are forced to turn to emergency rooms or "Medicaid mills" ¹⁵⁰ for care. Sophisticated ongoing treatments for HIV or AIDS patients can simply not be adequately provided at these locations. The absence of quality primary care, in turn, can frustrate efforts to manage more AIDS and HIV-infected patients on an outpatient basis. These byproducts of Medicaid's low reimbursement rates and absence of quality control could hamper the shift from inpatient to ambulatory care for AIDS patients.¹⁵¹

Medicaid reimbursement rates are set by the States and, thus, vary widely. They often do not cover the cost of care in outpatient

¹⁴⁶ *Medicaid Source Book: Background Data and Analysis*, Congressional Research Service, November 1988, p. 486; and "The Cost of AIDS in the United States," prepared by the Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, January 1988.

¹⁴⁷ "AIDS Health Care Financing and Services," by Mark Merlis, Congressional Research Service, Library of Congress (updated regularly).

¹⁴⁸ Jesse Green and Peter Arno, "The 'Medicaidization' of AIDS, Implications of the AIDS Payor Mix for Access and Quality," presented to the National Commission on AIDS, November 3, 1989.

¹⁴⁹ Despite evidence of widespread abuse, there has never been a formal review of the quality of ambulatory care provided to Medicaid patients by any State or Federal entity since the program's inception. (From a Preliminary Report on New York's Medicaid Program prepared for the Human Resources and Intergovernmental Relations Subcommittee, March 19, 1990.)

¹⁵⁰ Medicaid mills are small clinics that provide primary care. Forty percent of the physicians working in New York's Medicaid mills are not listed in the N.Y. State Medical Directory; many are not board-certified. In general the mills provide a very low level of care to poor persons who have few options. Hearing, "Quality of Care Provided by Medicaid Physicians in New York City," March 19, 1990, Human Resources and Intergovernmental Relations Subcommittee of the Committee on Governmental Operations, U.S. House of Representatives, galley pp. 73-75.

¹⁵¹ Op. cit., Green and Arno. See footnote 148.

clinics or private doctors' offices.¹⁵² One example of the disparity between private and Medicare physicians' payments on one hand, and Medicaid on the other, is in New York City, where an intermediate office visit by a new patient is compensated by Blue Cross at \$78, Medicare at \$80, and Medicaid at \$7.¹⁵³

However, New York State has taken significant actions in extending Medicaid eligibility to HIV-infected persons and offering competitive reimbursement rates for a range of early intervention services delivered at ambulatory care clinics.¹⁵⁴

The authors of a Medicaid study informally interviewed a group of physicians with large AIDS practices in New York. Most treat only a small number of Medicaid patients. Several of the physicians said they don't bill Medicaid for their services because the reimbursements are so small that it is not worth the time it takes to complete the paperwork.¹⁵⁵ This problem is exacerbated by the view that AIDS patients are more expensive to treat than other patients. Thus, some providers decide not to treat AIDS patients unless they have private insurance or can pay for services rendered.¹⁵⁶

AIDS care is financially risky to individual health care providers, hospitals, and other facilities due to its dependence on inadequate Medicaid reimbursements. The committee believes the Federal Government should explore ways to redirect the financing of AIDS care toward other payors including Medicare and private insurers.

Medicare inhibits AIDS coverage by requiring a 24-month waiting period for eligibility. Chairman Weiss has introduced legislation¹⁵⁷ that would waive this waiting period for persons with AIDS. Another legislative option would be to require private insurers to cover a larger share of the cost of AIDS care.

An alternative approach to resolving reimbursement rate inequities would be for the Federal Government to require higher rates and extend eligibility to other groups including HIV-infected persons, many of whom are not now covered. Legislation has been introduced in the House to accomplish part of this.¹⁵⁸

Medicaid may be better than no insurance at all, but it does not provide equal access to health care because Medicaid reimbursement rates are not comparable to private insurance, especially for primary care.

Several other problems with the Medicaid Program were raised at the subcommittee hearing. Foremost is the lack of coverage for many essential services recommended for optimum management of AIDS patients—services that can help to keep non-acute patients in the least restrictive settings. These include case management, nutritional services, personal care, subacute inpatient care, home-based health care and social services.¹⁵⁹ Fortunately, many of

¹⁵² Ibid.

¹⁵³ Ibid.

¹⁵⁴ "New Medicaid Reimbursement Rates for HIV Primary Care Visits," Memorandum, Health Facilities Series, New York State Department of Health, December 20, 1989.

¹⁵⁵ Ibid.

¹⁵⁶ "AIDS: Delivering and Financing Health Services in Five Communities," U.S. General Accounting Office, HRD-89-120, September 1989, p. 52.

¹⁵⁷ H.R. 416, introduced by Rep. Weiss, January 3, 1989.

¹⁵⁸ H.R. 4080, introduced on February 22, 1990, by Rep. Henry Waxman, and 44 co-sponsors.

¹⁵⁹ Hearing, July 28, Ms. McGuire, p. 197.

these uncovered services have been provided by volunteers in cities across the country. But there is not an unlimited supply of volunteers and many have reached the stage of burn-out and are unable to continue what is often physically and emotionally demanding work. Furthermore, volunteers are often scarce in the inner cities where the HIV epidemic is growing more rapidly.

Jean McGuire, Chair of NORA, the coalition of groups responding to the AIDS epidemic, suggested that the Health Care Financing Administration (HCFA) observe the experiences that HRSA has had with its HIV Service Demonstration Grants and apply that knowledge in reshaping the Medicaid Program. The Service Demonstration Grants are supporting coalitions of care providers who extend cost-effective services responsive to the many needs of the AIDS or HIV-infected patient.¹⁶⁰

Other problems are presented by administrative obstacles which prevent eligible persons from benefiting from Medicaid. Paul Jellinek of the Robert Wood Johnson Foundation, said at the hearing, "... this is an issue we've run into in Newark and Jersey City where they have . . . a fairly generous program, but because of bottlenecks at the county level in . . . getting people enrolled, a number of people are still not receiving those benefits."¹⁶¹

States can provide a more complete range of services to HIV patients through the optional Medicaid waiver program. Under the waivers, States can offer special service packages to certain groups of recipients such as those with AIDS. The waivers, authorized by Congress in 1981, were made more accessible for AIDS health care in 1986. The program allows a State to apply to HCFA for a Medicaid home and community-based services waiver or a waiver allowing them to provide case management services specifically to persons with AIDS. This waiver program is important because it allows reimbursement for many community or home-based health and social services that can prevent unnecessary and costly hospitalization. The State must be able to demonstrate that the proposed services are cost-neutral to obtain approval of the waiver. The State must also demonstrate that patients receiving care under the waiver would otherwise be hospitalized and that the per capita health care expenses would not be increased.¹⁶²

Cost-neutrality, required for the waiver, is one of the obstacles to obtaining waivers reported by States. States that routinely under-reimburse for health care services have a difficult time achieving cost-neutral programs to care for AIDS patients. Other barriers to the waiver include excessive paperwork and difficulty communicating with HCFA's headquarters and regional offices.¹⁶³ Texas has withdrawn its waiver application because it cannot demonstrate cost-neutrality constructing the waiver around community-based services.¹⁶⁴

¹⁶⁰ Ibid.

¹⁶¹ Hearing, July 28, Paul S. Jellinek, Ph.D., Senior Program Officer, The Robert Wood Johnson Foundation, p. 115.

¹⁶² *Medicaid Source Book: Background Data and Analysis*, Congressional Research Service, Library of Congress, November 1988.

¹⁶³ Hearing, July 28, Ms. McGuire, p. 209.

¹⁶⁴ Ibid.

Another shortcoming in the Medicaid Program is the lack of reimbursement for the so-called "off-label" use of drugs. Scientists are finding new and promising treatments for AIDS-related illnesses, but research results demonstrating safety and efficacy often precede formal FDA approval of the treatments by months or even years. Certain drugs, such as AZT, have been approved for one use, but research has demonstrated effectiveness for another off-label use.

The *treatment IND* provides early access to experimental drugs that are still undergoing clinical trials and have been deemed by the FDA to be adequately safe and effective for persons with AIDS and other life-threatening illnesses. There are other mechanisms through which persons with HIV infection and AIDS can obtain experimental drugs including the *open protocol* the *compassionate use IND*, and clinical trials themselves. The Public Health Service is currently developing an additional vehicle for providing access to experimental drugs, the parallel track. Even though many of these therapies are considered state-of-the-art, most are not reimbursed by Medicaid, Medicare or private insurers.

However, in September 1989, the U.S. Court of Appeals for the Eighth Circuit decided a case that will have bearing on off-label use of approved drugs. The court affirmed a lower court decision that the Missouri Medicaid Program must reimburse eligible persons for AZT, even if it is prescribed by physicians for uses not specified in its approval by the FDA. The court found in favor of plaintiffs who had AIDS but did not have the precise history or blood cell count, as specified by the FDA in its approval. Missouri Medicaid recipients had been denied reimbursement for AZT by the State on the grounds that any such off-label use was "experimental" and, therefore, not covered by the Medicaid Program.

Rejecting the argument that off-label usage is experimental, the court found:

The prescription of AZT beyond its labeled indications is not experimental. The record here establishes that physicians commonly prescribe AZT for patients who have neither a history of PCP nor a CD4 count below 200. . . . The Medicaid statute and regulatory scheme create a presumption in favor of the medical judgment of the attending physician in determining the medical necessity of treatment. In denying coverage of AZT . . . [the State has not] overcome that presumption except to rely on the FDA approval process in a manner expressly rejected by the FDA.¹⁶⁵

While this decision is binding only in the seven States in the Eighth Circuit, it will have a broad application to the off-label usage of prescription drugs. This issue has long been of concern to cancer patients and researchers.

The American Medical Association strongly endorses reimbursement for off-label use of drugs and for those drugs designated for treatment IND and compassionate use IND. Similarly, the Health Insurance Association of America recommends reimbursement for the off-label use of drugs based on information from standard medi-

¹⁶⁵ *Weaver v. Reagan*, 886 F.2d 194 (8th Cir. 1989).

cal compendia¹⁶⁶ or an analysis of scientific literature, if the drug or treatment does not appear in the compendia.¹⁶⁷

The committee believes that Medicaid should reimburse for the unlabelled use of FDA-approved drugs if that use has been established as state-of-the-art by scientists. The committee further believes that experimental drugs which have become the standard of care and are available under a treatment IND should also be reimbursed.

In spite of the plethora of problems raised at the subcommittee hearing, the National Commission on AIDS hearings, and other forums, HHS has failed to recognize the cost-effective and humanitarian results that Medicaid reforms could bring. HHS staff participated in an Intergovernmental Task Force on AIDS Health Care Delivery which was convened to identify and report on issues related to the care of persons with HIV infection. Of particular concern to the Task Force were "the availability and continuity of services and the identification of gaps in services."¹⁶⁸

The task force and its staff consisted of 37 senior staff from several Federal departments who met over the course of a year and, in January 1988, delivered a report to the Assistant Secretary for Health. The task force made 17 recommendations, including a suggestion that HCFA, "continue to examine Medicare and Medicaid policies related to reimbursement for AIDS patients."

The task force recommended that no changes be made specifically for AIDS patients in either the Medicaid or Medicare Program, due to the flexibility available to the States through Medicaid and "due to the extraordinarily high costs that would be incurred if changes were made to the Medicare and Medicaid programs."¹⁶⁹ Another reason presented for not changing Medicaid was:

The Medicaid program, even with its variations from State-to-State, stands as a final bulwark for those PWAs unable to obtain other financial means to pay for health care.¹⁷⁰

The committee finds that there are many problems with Medicaid—lack of coverage of necessary services, low reimbursement rates, bureaucratic barriers to coverage for eligible persons, and more—which prevent it from being the "final bulwark" that it should be. This is true not only for persons with HIV disease, but virtually all illnesses.

¹⁶⁶ American Hospital Formulary Service Drug Information; American Medical Association Drug Evaluations; and U.S. Pharmacopeia Drug Information.

¹⁶⁷ Minutes of the Seventh Meeting of the National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS, October 25, 1989, Bethesda, MD.

¹⁶⁸ *Report of the Intragovernmental Task Force on AIDS Health Care Delivery*, Department of Health and Human Services, January 1988, p. 1.

¹⁶⁹ *Ibid.*, p. 37.

¹⁷⁰ *Ibid.*

I. HIV INFECTION IS INCREASING AMONG DRUG USERS, THEIR SEXUAL PARTNERS, AND THEIR CHILDREN, THE MAJORITY OF WHOM ARE BLACK AND HISPANIC. HOWEVER, IT IS PERSONS IN THESE GROUPS WHO ARE LEAST LIKELY TO HAVE ACCESS TO HEALTH CARE

Of the estimated 1.3 to 1.5 million intravenous drug users in the United States,¹⁷¹ 36,790 have been reported as having AIDS as of the end of 1989.¹⁷² This number represents 27 percent of all AIDS cases reported to the CDC.¹⁷³ The majority of reported AIDS cases are among gay and bisexual men; however, in more recent years, reported cases among IVDU's, their sexual partners and their children, constitute an increasing proportion of persons with AIDS. The proportion of reported AIDS cases within these drug-related exposure categories has risen from 20 percent before 1985 to 33 percent in 1989. Reported cases among gay and bisexual men not using drugs has fallen from 65 percent before 1985 to 57 percent in 1989.¹⁷⁴

Blacks and Hispanics are overrepresented among reported AIDS cases, not only among IVDU's, their sexual partners and children, but also among gay and bisexual men.¹⁷⁵ The rate of AIDS per hundred thousand persons in 1989 was 34.7 for blacks and 26.3 for Hispanics as compared to 9.8 for whites.¹⁷⁶ Blacks represent 45 percent of all drug-related cases of AIDS including children, and Hispanics represent 26 percent.¹⁷⁷

In New York City, the newly-reported cases of AIDS traced directly to intravenous drug use outnumbers those transmitted through all other routes, and more blacks and Hispanics are developing AIDS than whites. Studies conducted in New York City drug treatment clinics have identified seroprevalence rates ranging from 17 percent to 65 percent of the persons tested.¹⁷⁸ By 1993, 50 percent of all new AIDS cases in New York City are expected to be in IVDU's. Gay and bisexual men will comprise 33 percent and the remaining 17 percent can be attributed to sex partners of IVDU's, and other causes.¹⁷⁹

The percentage of reported AIDS cases among women nationwide has risen from 7 percent in 1986 to 9 percent in 1990.¹⁸⁰ Most of these women acquire HIV infection through their own drug use (52 percent), or heterosexual sex with an intravenous drug user (19 percent). In New York, an even higher proportion of female HIV infection is related to these two activities.¹⁸¹ Eighty-four percent of

¹⁷¹ Report of the Presidential Commission on the HIV Epidemic, June 1988.

¹⁷² *HIV/AIDS Surveillance Report*, Centers for Disease Control, May 1990.

¹⁷³ *Ibid.*

¹⁷⁴ *HIV Disease: Health Care Policy Issues*, prepared for the American Foundation for AIDS Research, by the Institute for Health Policy Studies, University of California, San Francisco, February 1990.

¹⁷⁵ *HIV/AIDS Surveillance Report*, Centers for Disease Control, May 1990.

¹⁷⁶ *Ibid.*, January 1990.

¹⁷⁷ *Ibid.*, May 1990.

¹⁷⁸ Robert A. Hahn, Ida M. Onorato, et al., "Prevalence of HIV Infection Among Intravenous Drug Users in the United States," *Journal of the American Medical Association*, Vol. 261, May 12, 1989, pp. 2677-2684.

¹⁷⁹ *AIDS: The Challenge Facing the HHC System*, New York City Health and Hospitals Corporation, August 1, 1989.

¹⁸⁰ *AIDS Weekly Surveillance Report*, Centers for Disease Control, December 29, 1986, and *HIV/AIDS Surveillance Report*, May 1990.

¹⁸¹ Hearing, July 28, Dr. Rango, p. 158.

the AIDS cases among women in New York State, as of March 1990, are attributable either to the woman's own drug use or the drug use of her sexual partners.¹⁸² Nationwide, 52 percent of women with AIDS are black; 20 percent are Hispanic.¹⁸³

Children with AIDS are still a small proportion of total cases, but the number is growing rapidly. Only 95 cases of pediatric AIDS were reported to the CDC in 1984.¹⁸⁴ But, by the end of April 1990, 2,771 cases had been reported among children and adolescents. Of these, 2,258 were under 13 years of age, and 1,693 were under five. Of all children under 13 with AIDS, 83 percent acquired it perinatally from HIV-infected mothers.¹⁸⁵

By 1991, nearly 3,500 children are expected to have developed AIDS and about 20,000 will be HIV-infected.¹⁸⁶ According to CDC seroprevalence studies, as many as 2,000 infected infants are born each year.

Minority children are affected most. Black children constitute 15 percent of all children in the United States, but represent 53 percent of reported pediatric AIDS cases. Hispanic children, who are 10 percent of all U.S. children, account for 25 percent of children with AIDS.¹⁸⁷

The major locale for substance abuse is poor neighborhoods of the Nation's larger cities. The President's Commission on the HIV Epidemic stated in its report that:

Witnesses before the Commission presented considerable evidence that the occurrence of drug abuse, particularly intravenous heroin abuse, is frequently found in communities where poverty and crime are endemic. It has been noted that persistent poverty in the midst of an affluent society engenders hopelessness and despair which can lead to [drug] abuse and related high rates of crime.¹⁸⁸

Drug abuse and AIDS in the inner city must be viewed in context. In addition to drugs and AIDS, the urban health care crisis also includes alcoholism, mental illness, homelessness, tuberculosis, sexually transmitted diseases (STD's), teenage pregnancy, infant mortality and hunger.¹⁸⁹ In addition, blacks and Hispanics are burdened with excess morbidity and mortality related to cancer, cardiovascular disease, diabetes, cirrhosis and homicide.¹⁹⁰

Despite these medical and psychological burdens, it is within the inner city that the U.S. health care system has served its clients least well. Barriers to health care for poor people in urban centers existed prior to the epidemic, but AIDS has exacerbated them. It is

¹⁸² *AIDS Surveillance Monthly Update*, New York State Department of Health, March 1990.

¹⁸³ *HIV/AIDS Surveillance Report*, Centers for Disease Control, January 1990.

¹⁸⁴ *AIDS Weekly Surveillance Report*, December 1984.

¹⁸⁵ *HIV/AIDS Surveillance Report*, Centers for Disease Control, May 1990.

¹⁸⁶ "1990 Legislative Agenda," Pediatric AIDS Coalition, January 1990.

¹⁸⁷ *HIV/AIDS Surveillance Report*, Centers for Disease Control, January 1990.

¹⁸⁸ *Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic*, June 1988, p. 93.

¹⁸⁹ Dr. Sa-Hoi Lam, Hill Haven Health Center, New Haven, CT, testimony before the National Commission on AIDS, November 3, 1989, Washington, D.C., pp. 461-464.

¹⁹⁰ Report of the Secretary's Task Force on Black and Minority Health, Department of Health and Human Services, Vol. I, August 1985, pp. 70-78.

poor blacks and Hispanics in the inner cities who have the least access to care.¹⁹¹

Dr. June Osborn, Chairman of the National Commission on AIDS, after visiting New York's shelters to find out about health care and HIV infection, recounted her reactions:

I thought . . . that I had seen it all, but . . . I realized that even central Africa paled in comparison to some of what is happening in the shadow of the Statue of Liberty! We are seeing drugs and poverty and hopelessness—and now HIV and AIDS—threaten to complete the investiture of an “underclass” in our once-proudly classless land of opportunity.¹⁹²

Dr. Osborn's statement also represents the testimony of many witnesses at the subcommittee's AIDS hearings who work in hospitals, clinics and drug treatment programs in cities impacted by the epidemic. A physician at Harlem Hospital in New York described her frustration at the lack of resources to meet the need for health care in her own community:

The word “crisis” has been used to describe the state of the health care system for the urban poor of this country. The word is used so frequently that it fails to generate action. Yet, I feel compelled to use it when speaking of the AIDS epidemic in communities like Harlem.¹⁹³

. . . Their precarious situation may be gauged by the fact that fully 50 percent of our patients are functionally homeless. They lack a social or support network to help them cope with . . . [AIDS]. They also have traditionally had only sporadic access to an overburdened public health care system. Their health care provider is often the emergency room of the local municipal hospital. Thus, it is that responding to even the most urgent needs of our AIDS patients in Harlem requires an effort and resources beyond that of the typical [non-poor] AIDS patient.¹⁹⁴

Many poor patients do not have private physicians and have only limited access to outpatient clinics. They are often forced to resort to hospital emergency rooms for medical care. HIV infection rates among patients using emergency rooms for primary care are high.

One study conducted among emergency room patients at Johns Hopkins Hospital in Baltimore showed that the incidence of HIV infection doubled between 1986 and 1988. The seroprevalence rate was 6 percent, up from 5.2 percent in 1987 and 3 percent in 1986. Unfortunately, most of these patients are “silent carriers” who do not know they are infected.

The Baltimore data also support other national data that indicate the epidemic is shifting toward blacks and Hispanics. The black patients entering Johns Hopkins' emergency room are more

¹⁹¹ “Access to Health Care in the United States: Results of a Survey,” Robert Wood Johnson Foundation Special Report, Number 2, June 1987.

¹⁹² Dr. June Osborn, Chairman, National Commission on AIDS, testimony before the House Budget Committee Task Force on Human Resources, March 6, 1990.

¹⁹³ Hearing, July 28, Dr. El-Sadr, p. 118.

¹⁹⁴ *Ibid.*, p. 116.

than twice as likely to have an unrecognized infection as the white patients. In 1988, over 16 percent of black male patients between the ages of 30 and 34 were seropositive. Black men in a wider age range are also greatly affected: more than 1 in 10 between the ages of 25 and 45 are infected. Even among black women at Johns Hopkins in this age range, 5 to 6 percent are seropositive.¹⁹⁵

With the growing number of AIDS cases, the new benefits of expensive early intervention treatments, and the lack of adequate health care and related services, the committee finds that financing is the dominant issue in the delivery of care to persons with HIV. But there are now actually two health care systems: one for those who can afford good care and one for the poor, who cannot. If the economics of the AIDS epidemic are not addressed, in part through the Medicaid Program, these injustices in our health care system will continue and be exacerbated.

Early recognition of HIV infection and prevention treatment hold out the promise of a longer AIDS-free life. But in spite of clear indications that the epidemic is increasing in intensity among drug users, blacks and Hispanics, the promise of early intervention¹⁹⁶ is in large part denied them.¹⁹⁷ Without strategies that address the specific needs of HIV-infected persons in the inner cities and the difficulties of providing care for them, early intervention will pass them by.¹⁹⁸

Dr. Wafaa El-Sadr, of Harlem Hospital, spoke of the need for resources to address the special problems of her patients if early intervention is to be offered:

. . . In spite of the scientific advances in AIDS therapy of the last few years, in communities such as Harlem we find ourselves less—not more—capable of coping with the epidemic. We are struggling to provide the quality of care that we believe should be available to all. We want to implement the new recommendations. But we can succeed only if due regard is given to the special needs of our communities. . . .¹⁹⁹

There are distinct problems in treating pregnant, HIV-infected women in inner-city hospitals. The number of seropositive women having babies is growing. Dr. Donald Craven testified at the hearing that one out of every 40 women giving birth at Boston City Hospital is now HIV-infected.²⁰⁰ At New York's Harlem Hospital, about 3,000 babies are delivered each year. Seroprevalence studies indicate that in 1988, from 120 to 150 (as many as one out of 20) of the mothers of these babies are infected. Thirty to fifty percent of their babies develop AIDS. Dr. Janet L. Mitchell, Harlem's Chief of Perinatology said at the subcommittee's pediatric AIDS hearing that these would be "devastating numbers for the most affluent hospital taking care of the most affluent patients, but our patients

¹⁹⁵ Gabor D. Kelen, Johns Hopkins Hospital, "The AIDS Epidemic: Public Health and Emergency Medical Care Issues," testimony before the Subcommittee on Health and the Environment, Energy and Commerce Committee, U. S. House of Representatives April 4, 1989.

¹⁹⁶ See finding A on page 6 for a discussion of early intervention.

¹⁹⁷ Hearing, July 28, Dr. Brown, p. 67.

¹⁹⁸ *Ibid.*, Dr. El-Sadr, p. 116.

¹⁹⁹ *Ibid.*, p. 118.

²⁰⁰ Hearing, July 28, Dr. Craven, p. 151.

come from poverty, homelessness, and illiteracy, and their babies are born premature, drug . . . [exposed], and in poverty.”²⁰¹

Harlem's department of obstetrics and gynecology offers medical services, pediatric care, counseling, testing, and social services to a group of very high-risk mothers who have received little or no prenatal care. These mothers most often make their first visit to the hospital when they are ready to deliver. Nearly 80 percent of the women are drug users, some of whom have had numerous STD's. During the first weeks this program was in operation, staff discovered that 50 percent of the women who agreed to be tested were HIV seropositive. They also discovered that the needs of the patients and their families were so great that the staff could not accommodate all the eligible women. The program is funded with a Maternal and Child Health (MCH) grant from HRSA. Because the MCH program did not receive an increase in funding in fiscal year 1989, neither did the Harlem Hospital program. They were forced to turn away even more women who needed care.²⁰²

Harlem Hospital also runs a clinic for chemically dependent, pregnant women which increased its caseload by 150 percent in 1988, in spite of the lack of resources to increase staff.²⁰³ The growth in the number of female drug users is, in large part, associated with the increase in the use of crack cocaine. Crack appeals to some women who do not want to use IV drugs. Crack in turn is linked with sexual activity and thus HIV infection.²⁰⁴

The committee finds that the epidemic has underscored the weaknesses and deficiencies in the U.S. health care system and most particularly the inequality of access to quality primary care for many Americans, especially those who are poor and members of racial minorities. More and better resources are desperately needed in almost every area of health care and social and psychological services to treat poor, inner city persons with HIV infection and AIDS who do not need hospitalization.

The list of resource needs would be incomplete if it did not make reference to the acute need for housing. A witness at the subcommittee hearing on pediatric AIDS described the housing problems faced by HIV-infected persons. Mary Boland of Children's Hospital in Newark, NJ, said that some of the children and families in the hospital-based AIDS treatment program she directs are ready for discharge but cannot receive services at home because the homes are in such poor physical condition or because the neighborhood is not safe enough for the health care worker to go there. This can result in extending hospitalization unnecessarily or in depriving patients of needed services. She described an 8-month old baby who is ready to go home but cannot because her mother lives in an abandoned building with no heat or hot water.²⁰⁵

The lack of adequate housing for poor families in the inner cities is a national disgrace exacerbated by the scourge of AIDS. Every level of government should be mobilized, led by Washington. The committee calls on the administration to lead the Nation in resolv-

²⁰¹ Hearing on "Children and HIV Infection," op. cit., Dr. Mitchell, p. 27. See footnote 97.

²⁰² Ibid.

²⁰³ Ibid.

²⁰⁴ Ibid.

²⁰⁵ Ibid., Ms. Boland, p. 35.

ing the low-income housing crisis so that situations such as those described here will no longer occur.

While much remains to be achieved in reducing HIV transmission among gay men, there has been significant progress where effective education programs have resulted in modified behavior.²⁰⁶ IVDU's and their sexual partners offer a more arduous challenge for they have no advocacy groups and no support organizations to provide prevention education.²⁰⁷ ²⁰⁸ IVDU outreach projects such as those sponsored by the National Institute on Drug Abuse (NIDA) must be continued and expanded for they are beginning to demonstrate that risk reduction among IVDU's is possible.²⁰⁹

J. LINKAGES BETWEEN DRUG ABUSE TREATMENT PROGRAMS AND PRIMARY CARE MUST BE ESTABLISHED TO RESPOND TO THE MANY HEALTH CARE NEEDS OF DRUG USERS

In addition to the disease of drug addiction, intravenous drug users more often experience a variety of medical afflictions including tuberculosis, endocarditis, bacterial pneumonia, STD's and hepatitis, many of which are exacerbated by HIV immunosuppression.²¹⁰ As HIV infection has increased among this population, their need for primary health care has increased dramatically. But many IV drug users have not availed themselves of health care provided by traditional health care facilities and, on the other hand, many health care providers have not reached out to offer assistance to addicts. It is necessary to develop strategies to bring drug users into a health care system that is designed to meet their particular needs.²¹¹

At the subcommittee hearing, virtually all the witnesses from health care agencies, and others, strongly recommended that drug treatment programs offer primary care to their clients, or, if that is not possible, develop close linkages with primary care providers through referrals.

Peter Arno, a health economist, also argued that drug abuse and HIV disease must be managed together:

We must seriously begin to address the twin tragedies of drug abuse and HIV disease. If we do not, we will never solve or end the AIDS epidemic. Aside from expanding treatment capacity, which we must do, we must integrate

²⁰⁶ Coutinho, R., van Grievsen, G.J.P., Moss, A., et al., "Effects of Prevention Efforts Among Homosexual Men," *AIDS*, Vol. 3 (supp. 1), 1989, pp. S.53-S.56.

²⁰⁷ Hearing, July 28, Dr. Craven, p. 133.

²⁰⁸ Dr. Samuel R. Friedman and others at the Narcotic and Drug Research, Inc., and ADAPT in New York City have initiated a project to organize IV drug users. Results show that "IV drug users can and will try to protect others against AIDS and that projects should be developed that enlist their skills and energies to do so." From "Collected Self-Organization as a Strategy Against AIDS," S.R. Friedman, D.C. Des Jarlais, et al., to be presented at meetings of the International Sociological Association, Madrid, Spain, July 1990. This project was funded by NIDA and the New York State Division of Substance Abuse Services.

²⁰⁹ "Effects of Outreach Intervention on Risk Reduction Among Intravenous Drug Users," Alan Neaigus, Meryl Sufian, et al., in press, *AIDS Education and Prevention*.

²¹⁰ Rand L. Stoneburner, Don C. Des Jarlais, et al., "A Larger Spectrum of Severe HIV-1-Related Diseases in Intravenous Drug Users in New York City," *Science*, November 11, 1988, Vol. 242, pp. 916-919.

²¹¹ "Demonstration Grants for the Provision of Integrated Community-Based Primary Care and Drug Abuse Treatment: Program Guidance," Bureau of Health Care Delivery and Assistance, Health Resources and Services Administration, Department of Health and Human Services, May 1989.

primary medical care in our inner cities with drug treatment programs. Conversely, we ought to be thinking about providing drug treatment services in our primary care settings. These initiatives are just beginning to be thought about but we need to move strongly and forcefully on them immediately.²¹²

In fact, this concept was promoted by the President's Commission on the HIV Epidemic. In its final report, published in June 1988, the Commission recommended linkages between drug abuse treatment on the one hand and health care and social and psychological assistance on the other hand and suggested that case managers should coordinate the services.²¹³

At the time of the hearing, New York State was beginning to offer health-related services along with drug treatment. Counseling and testing programs were set up within 14 hospital and community-based drug treatment centers. Medical and support referral linkages will be developed for each of the centers with a view toward providing comprehensive services to the seropositive addicts in treatment.²¹⁴

Dr. Donald Craven's clinic at Boston City Hospital offers an array of coordinated services provided by nurses, physicians, social workers, addiction counselors, nutritional support personnel, AIDS action advocates, and psychologists. Assistance is provided in obtaining housing and other basic services. Dr. Craven told the subcommittee that his clinic would like to provide early intervention to patients who are HIV-infected, but resources allow only treatment for symptomatic patients.²¹⁵

In the Boston metropolitan area, fewer than 500 of the estimated 14,000 IVDU's had been tested for HIV by the summer of 1989. In order to reach out to this group, Project TRUST²¹⁶ was launched at Boston City Hospital under the joint sponsorship of several State and city agencies. The staff of nurses, counselors, and outreach workers provide counseling, testing (for HIV, tuberculosis, and pregnancy), and social services, medical evaluation and referrals to drug and alcohol treatment. Project TRUST is located in a neighborhood in which drug users are comfortable and provides its services free of charge.²¹⁷

In its first year of operation, 635 clients received HIV testing and counseling. Seventeen percent tested positive. Of the 635 who were tested, 79 percent returned for test results and counseling.²¹⁸

The Morbidity and Mortality Weekly Report (MMWR), published by the CDC, recognized Project TRUST. It stated that program components which contribute to Project TRUST's success are the broad spectrum of services available without appointment and

²¹² Hearing, July 28, Peter S. Arno, Ph.D., Health Economist, Department of Epidemiology and Social Medicine, Montefiore Medical Center, Albert Einstein College of Medicine, p. 104.

²¹³ Report of the Presidential Commission on the HIV Epidemic, June 1988, p. 97.

²¹⁴ Hearing, July 28, Dr. Rango, p. 164.

²¹⁵ *Ibid.*, Dr. Craven, p. 135.

²¹⁶ Project TRUST stands for Teaching, Referral, Understanding, Support, and Testing.

²¹⁷ Hearing, July 28, Dr. Craven, p. 135.

²¹⁸ *Morbidity and Mortality Weekly Report*, Centers for Disease Control, Vol. 38, July 21, 1989, pp. 489-96.

without charge, the presence of former drug users on the staff, and anonymity. According to the MMWR:

The high percentage (79%) of IVDU's who returned for their test results indicates that HIV prevention measures can be effectively provided to IVDU's if services are tailored to the specific needs and circumstances of this high-risk group.²¹⁹

Dr. Craven testified that such compliance can also be achieved in clinical trials if the appropriate services are offered. He characterized the compliance rate among IVDU's in Boston City Hospital's clinical trials as "excellent."²²⁰

There are signs that the Public Health Service recognizes the importance of making drug treatment and primary care available to drug users in one facility. A collaborative effort of the Bureau of Health Care Delivery and Assistance in HRSA, and the National Institute of Drug Abuse in ADAMHA, has awarded a total of \$9 million to 21 grantees who will offer a wide spectrum of care to drug users, their sexual partners and families. Community based, this program will integrate intravenous drug abuse treatment and comprehensive primary care in one location, and will also include prevention education and early intervention. For example, a drug-using, pregnant woman could enter a drug treatment program, get prenatal care, and receive HIV prevention information. If she is HIV positive, she can obtain treatment to prevent the onset of AIDS.²²¹

The committee finds this new program to be an excellent example of collaboration between agencies in the Public Health Service. However, because of the great need for primary care among IVDU's and their families, the funding allocated thus far is much too low to make significant inroads into the health care problems of this population. Not only drug users, but all persons with HIV infection and AIDS require a continuum of care that single agencies cannot easily support alone. Additional efforts such as this cooperative program should be encouraged by PHS with financial and administrative support.

K. INTRAVENOUS DRUG USERS, WOMEN AND PEOPLE OF COLOR CONTINUE TO BE UNDERREPRESENTED IN CLINICAL TRIALS FUNDED BY NIAID

People of color, drug users, and women are not enrolled in clinical trials of HIV-related drugs in proportion to their representation among AIDS cases reported to the Centers for Disease Control. The National Institute of Allergy and Infectious Diseases (NIAID) funds the majority of federally sponsored clinical trials. According to NIAID, on February 19, 1990, 11 percent of enrollees were black, as compared with 27 percent of the reported AIDS cases. Hispanics represented 11 percent of the patients in NIAID's clinical trials, but are 16 percent of all AIDS cases.²²²

²¹⁹ Ibid.

²²⁰ Hearing, July 28, Dr. Craven, p. 134.

²²¹ Ibid., Dr. Smith, pp. 130-131.

²²² "Demographic Information for Active Patients as of February 19, 1990," AIDS Clinical Trials Group, National Institute of Allergy and Infectious Diseases, and the *HIV/AIDS Surveillance Report*, Centers for Disease Control, February 1990.

IVDU's, former and current, are also underrepresented in NIAID's clinical trials. Of the 6,534 patients enrolled, 0.5 percent are current users and 9 percent reported previous intravenous drug use.²²³ These numbers represent little improvement since the committee issued its report, "AIDS Drugs: Where Are They?" in 1988.²²⁴ In fact, the percent of drug users in clinical trials has dropped from 12 percent in August 1988²²⁵ to 9.5 percent in February 1990.²²⁶

Not only does their underrepresentation in clinical trials deny members of these groups opportunities for optimum medical care and experimental treatment, but it also denies scientists the opportunity to study the effects of drugs on all the populations most at risk.

Dr. Lawrence Brown, a physician who works with IV drug users, argues that participation in clinical trials offers a level of care not generally available in publicly funded clinics and some privately funded facilities and that such participation also offers emotional and psychological support.

And Dr. Brown added:

. . . For us to have drugs that are going to have the widest application, we have to test them in populations . . . where they are more likely to be utilized.²²⁷

Clinical trials are most often conducted at academic medical centers many of which have not reached out to poor persons, people of color, and drug users for clinical trials. Dr. El-Sadr, from Harlem Hospital told the subcommittee that:

. . . The availability of . . . [clinical trials of new therapies] in communities such as Harlem has been negligible.

* * * * *

. . . [There is a] reluctance to implement the new protocols in these communities. Yet, to thus exclude these communities from these protocols is not only inappropriate social policy, it is bad public health practice and even poor science. To exclude from these protocols, *ex ante*, one of the key target groups for the therapy is to introduce uncertainty both about the clinical effect of the therapy and the ability of the therapy to be implemented in this group.

The solution cannot be to exclude communities such as Harlem from these protocols, but rather to provide the human and financial resources necessary to allow the intensive programs necessary to implement these protocols successfully.²²⁸

It is apparent that with supplementary support services to help poor people, drug users, and others participate in clinical trials,

²²³ Ibid.

²²⁴ "AIDS Drugs: Where Are They?" Seventy-third Report of the Committee on Government Operations, House Report 100-1092, 100th Congress, 2d Session, October 1988.

²²⁵ Ibid.

²²⁶ Op. cit. See footnote 222.

²²⁷ Hearing, July 28, Dr. Brown, p. 68.

²²⁸ Ibid., Dr. El-Sadr, pp. 117-118.

compliance can be achieved. About one-third of Dr. Donald Craven's Boston City Hospital patients are enrolled in clinical trials. They are drug users. He maintains that their 80 percent compliance rate has been "excellent," and believes his experience is similar to that in other centers where the continuing primary care essential to keep people in the trials is offered to them.²²⁹ Several recent studies also report acceptable rates of compliance in treatment and with implications for clinical trials.²³⁰

Dr. Rango, Director of the New York State AIDS Institute, repeated the observation: "... the empirical evidence is growing that substance users, particularly those who are HIV infected, represent people who can be treated the same as anyone else and that a philosophy of therapeutic nihilism with respect to this population must finally be put to rest."²³¹

The committee finds that without health-related services including primary and psychological care and support services such as transportation, day care, the enrollment and retention of drug users and other underrepresented groups in clinical trials will be very difficult. The committee believes that it is the responsibility of the Public Health Service to ensure that such services are offered, in part through coordination between NIH and appropriate programs conducted by HRSA, through consultation with the Health Care Financing Administration regarding Medicaid and Medicare reimbursements for experimental treatments, and consultation with the appropriate congressional committees. While greater access to clinical studies will not solve the problem of inadequate access to medical care, it will be a step forward.

Studies have demonstrated that therapeutic drugs that are efficacious in one population or gender are not necessarily so in another.²³² Ongoing studies and those already concluded are based in large part on participants who are white, male homosexuals, while the epidemiological trends demonstrate the epidemic is growing among minority populations that include women and drug addicts as well as gay and bisexual men.²³³ Environment and culture can have an effect on research results. Research done among limited populations cannot be expected to produce results that always apply to the population at large.²³⁴

The committee finds that the underrepresentation of people of color, drug users, and other groups is not only inequitable, but it is also questionable science.

Scientists do not know if AIDS drugs are processed differently in women. While the percentage of women enrolled in clinical trials—8.6 percent on February 19, 1990²³⁵—is closer to the percentage of

²²⁹ Ibid., Dr. Craven, p. 135.

²³⁰ Peter A. Selwyn, Anat R. Feingold, et al., *Annals of Internal Medicine*, Vol. III, November 1, 1989, pp. 761-763; J. Samuels, M. Hilton, et al., "Home Aerosolized Pentamidine Prophylaxis in an Inner City Population," presented at V International Conference on AIDS, Montreal, June 1989; J. Samuels, J. Hendrix, et al., "Update on AZT Therapy in an Inner City Population," presented at V International Conference on AIDS, Montreal, June 1989; I. Williams, J. Noel-Connor, et al., "Compliance with Zidovudine (AZT) Therapy in an Inner-City HIV-Infected Population," presented at V International Conference on AIDS, Montreal, June 1989.

²³¹ Hearing, July 28, Dr. Rango, p. 154.

²³² Ibid., Dr. Brown, p. 76.

²³³ *HIV/AIDS Surveillance Report*, Centers for Disease Control, January 1990.

²³⁴ Dr. Janet L. Mitchell, testimony before the Committee to Study the AIDS Research Program of the National Institutes of Health, Institute of Medicine, December 5, 1989.

²³⁵ NIAID, op. cit. See footnote 222.

all AIDS cases reported among women—9 percent as of April 1990—the number of HIV-infected women is rapidly increasing. The slow increase in female trial participants reflects the attitudes and practices in other areas of biomedical research where women are deliberately excluded.²³⁶ The committee finds that NIAID has not provided the necessary outreach and support services to promote the participation of women in clinical trials.

NIAID has responded to the committee's earlier report and to the need among underserved populations for greater access to clinical trials by creating the Community Program for Clinical Research in AIDS (CPCRA), now in its first program year. Funded at \$9 million, it supports 18 treatment research programs based in 14 cities where large numbers of people with AIDS live and receive medical care. Community-based physicians and their patients are being enlisted in clinical trials of new drug therapies to fight AIDS and its opportunistic infections. The program is designed to reach out to blacks, Hispanics, women, and intravenous drug users.²³⁷

The committee believes that this fledgling program shows much promise and that with an adequate funding level could help to a greater extent meet the need for clinical research by community-based physicians. A higher funding level would help meet the need for greater access to treatment for underserved groups and enhance clinical research involving members of underserved groups providing needed information on the effects of new treatments.

Low-income persons have limited access to health care. Another way to enhance opportunities for the participation of such persons in clinical trials is to locate CPCRA projects in those cities where HRSA's HIV Service Demonstration Grant Programs are located. These programs support and coordinate community-based services that provide supportive services and health care for many of the persons who would participate in CPCRA trials. Linkages between CPCRA projects and Community Health Centers could also facilitate meeting the primary care needs of patients enrolled in clinical trials.²³⁸

III. CONCLUSIONS

The committee finds that the HIV epidemic has illuminated the profound inadequacies and weaknesses in America's health care system—especially the inequality in access to care for many of us, most often those of us who are poor and those who are black or Hispanic. A national health plan is a long way from reality, for its planning has been turned over by the administration to commissions and committees and a consensus may be years away.

The Federal response to the HIV epidemic thus far demonstrates that the Government, often bound by moralistic ideology, is still unprepared to respond to this crisis. We are in the tenth year of the HIV epidemic and yet have not adequately confronted the com-

²³⁶ "A Look at Research Involving Women," Sally Squires, *Washington Post*, December 12, 1989.

²³⁷ "Community Programs for Clinical Research on AIDS," *Backgrounder*, NIAID, October 1989.

²³⁸ Jean Flatley McGuire, AIDS Action Council, and Steve Smith, Human Rights Campaign Fund, testimony before the Committee to Study the AIDS Research Program of the National Institutes of Health, Institute of Medicine, December 4, 1989.

plex health and social service needs of affected persons and their families. The resolution of the problems of caring effectively, efficiently, and compassionately for those with HIV disease will not be easy, nor inexpensive. But, if we can navigate the universe, we can find ways to treat and care for our citizens. We have, as the Assistant Secretary of Health stated, the "moral responsibility" to do so.

At the end of the 2 days of hearings on treatment and care for persons with HIV disease, Chairman Weiss told the Federal witnesses:

. . . ultimately you cannot—the Federal Government cannot—hide from this responsibility [for treating and providing care to persons with HIV disease]. It is coming our way. I must tell you, when you see the shambles that the health care system is going to be in, in a number of cities across this country, you and I and all of us in the Federal service are going to be held responsible. We will not even be able to plead ignorance, because, in fact, we have been on fair notice.

It is with that sense of concern and urgency that I wish to end this hearing today.²³⁹

IV. RECOMMENDATIONS

1. Since the beginning of the AIDS epidemic, health care providers, Members of Congress, national health organizations, cities, States, and the persons directly affected by AIDS have called on the Federal Government for leadership. In their reports, the Institute of Medicine of the National Academy of Sciences, the Presidential Commission on the HIV Epidemic, the National Commission on AIDS, and this committee have urged the Government to provide leadership. It is clear from the extra burdens that the epidemic has placed on an already crumbling U.S. health care system that national leadership in the effort to provide treatment and care for affected persons is needed more than ever.

The Public Health Service will spend an estimated \$1.6 billion on AIDS in fiscal year 1990. This is an increase of \$300 million over the previous year. There is no question that funds have been spent, and that advances have been made—especially in AIDS research. Nonetheless, leadership has not been forthcoming. Through two Administrations, neither the President nor any other Federal official, at the highest levels to which the American public looks for direction in times of crisis, has taken responsibility for the strategic planning necessary to control the epidemic and provide treatment and care to its casualties. We urge the President to provide the overarching leadership that is fundamental to winning the fight against AIDS.

2. The Medicaid Program, according to the Intragovernmental Task Force on AIDS Health Care Delivery, is expected to be the "final bulwark" for those low-income persons with HIV infection who are uninsured and cannot pay for health care, as it should be for persons with all kinds of illness and injury. If this is so, then it should be modified to (a) reach more uninsured, poor Americans in

²³⁹ Hearing, August 1, Chairman Weiss, p. 319.

need of care, including those with HIV infection, (b) provide reimbursements to health care facilities that more fully meet the cost of services, (c) cover essential services that will help to keep non-acute patients out of the hospital, (d) require that States provide a level of service that will adequately care for the sick and injured, and (e) reimburse for state-of-the-art experimental or off-label treatment when there is no other treatment available or appropriate.

3. The Federal Government responds to natural disasters such as earthquakes and hurricanes, as well as man-made disasters such as oil spills, by providing billions of dollars in disaster assistance to affected communities. The Federal Government should offer disaster assistance to all those localities hardest hit by the AIDS epidemic, with assurances that funds will continue to flow until the epidemic abates.

4. Health care experts recommend coordinated services, referred to as a "continuum of care," for persons with HIV disease. Services that include HIV prevention, testing and counseling, early intervention, primary care, and, where appropriate, drug treatment, should be provided through community-based facilities in localities where HIV is endemic. Ideally, these services should be offered in a single facility to make it easier for patients to obtain assistance. HHS should create linkages between agencies that fund these services using as a model the Integrated Community-Based Primary Care and Drug Abuse Treatment Program which was developed jointly by staff in HRSA and NIDA.

5. Community health centers are located in neighborhoods more likely than others to be impacted by AIDS. These centers can play a pivotal role in delivering ambulatory care to persons with HIV disease. In order to meet rapidly escalating costs and to maximize success in caring for HIV patients, the funding levels for community health centers should be increased—both the basic grants, as well as funding specifically for AIDS.

6. Intravenous drug users experience a variety of illnesses which are exacerbated by immunodeficiency as a result of HIV infection, and yet they are often not patients in the health care system. For these reasons, the Federal Government should support primary care services offered at locations in the communities where drug treatment programs are offered or with strong linkages to drug treatment facilities in communities where drug abuse is a problem. One good example is the mobile van that can go directly into neighborhoods with high incidence of drug use.

7. As the epidemic spreads among groups underserved by the health care system, outreach to these individuals is essential. NIDA has sponsored outreach intervention that is demonstrating that risk reduction among IV drug users is possible. The Federal Government should expand its support of outreach programs for intravenous drug users and extend them to women, adolescents, and others who are not receiving health care services, to offer HIV prevention education, drug treatment, primary care, and social services where needed.

8. Minorities, IV drug users, women, and children are under-represented in clinical trials sponsored by NIAID. There are several reasons for increasing the number of participants from these

groups. Underrepresentation denies these persons opportunities to obtain the newest promising therapy and optimum medical care. It also denies scientists the opportunity to examine the possibility of disparate effects of new treatments on different populations. NIAID should continue its efforts to increase participation of minorities, IVDU's, women, and children in clinical trials and provide health and social services when needed to encourage participation.

DISSENTING VIEWS ON HON. RICHARD K. ARMEY, HON. AL McCANDLESS, HON. HOWARD C. NIELSON, HON. J. DENNIS HASTERT, HON. JON L. KYL, AND HON. CHUCK DOUGLAS

We commend the Human Resources Subcommittee for producing an excellent report on the current status of AIDS care and treatment in the United States. However, since we disagree with many of the report's recommendations, we dissent.

The first recommendation that the President provide the over-arching leadership that is fundamental to winning the fight against AIDS implies that the President has been AWOL in this fight. However, while we may not always agree with the President on this issue, nothing could be further from the truth.

Direct and indirect Federal funding for AIDS has been increasing every year, and these increases have been accepted by the President despite tremendous demands for more resources to treat other diseases adversely affecting many more Americans each year. In addition, President Bush's leadership was instrumental in seeing that the Americans with Disabilities Act contained anti-discrimination provisions to protect victims of AIDS. AIDS activists have demanded this protection for years, and we believe it is fair to say that without President Bush's leadership and support, this provision never would have become law.

Unfortunately, the response to President Bush's leadership in many AIDS activist communities has been scorn. These activists want nothing less than President Bush's complete acceptance of their far reaching legislative agenda, and anything less invites their contempt. Evidence of this contempt was provided earlier this summer when activists shouted down Secretary of Health and Human Services Louis Sullivan at the International Conference on AIDS held in San Francisco, and prevented him from being heard.

Many of our additional concerns are based upon philosophical differences in the direction we would like to see health care move in the United States. We believe that many of the current weaknesses in our health care delivery system are the direct result of piecemeal government socialization of health care in our nation. While the report's recommendations might be the best approach for AIDS care in a world of universal government-provided health care, that is not the world we are in today. Furthermore, we believe moving closer to this world should be avoided because we are convinced its overall costs are certain to outweigh its benefits.

Specifically, we are concerned with the report's recommendation that Medicaid reimburse for state-of-the-art experimental or off-label treatment when there is no other treatment available or appropriate. While we applaud the Human Resources Subcommittee's newfound concern with burdensome drug regulations that prevent people from obtaining the help they need, we are reluctant to open

a new Federal funding pipeline for treatments that don't work or may be nothing more than pure quackery. We simply cannot support a recommendation that would give AIDS patients preferential treatment over other persons who may have different, but no less serious, diseases.

Our next concern involves the report's recommendation that localities hard hit by AIDS receive seemingly perpetual disaster assistance aid. While some of us voted for the AIDS emergency funding bill considered by the House earlier this year, supporting this recommendation for continued open-ended funding does not merit our support.

Clearly, AIDS is not a natural disaster like hurricanes or earthquakes; the overwhelming majority of AIDS cases can be prevented through modifications in individual behavior. While it is true that the Federal Government reimburses localities for man-made disasters like oil spills, aid is usually accompanied by legislative initiatives to prevent the disaster from spreading or occurring again. Localities should clearly demonstrate that they are taking concrete public health measures to prevent the continued growth of AIDS in their communities. Without these assurances, we do not believe additional "disaster" assistance should be provided.

Finally, although we recognize that the report's focus was on the treatment side of the equation, we sense an underlying shift away from the prevention side. It cannot be repeated too often that the best cure for AIDS, the best treatment for AIDS and the best solution to AIDS is not practicing behavior that places a person at risk. There's a lot of good to be said for respecting traditional family values, entering monogamous relationships and avoiding the evils of drugs. Unfortunately, so long as we continue as a nation to move away from these values, we're afraid that the fight against AIDS will get tougher.

DICK ARMEY.
AL McCANDLESS.
HOWARD C. NIELSON.
J. DENNIS HASTERT.
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